

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

**March 19, 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 March 19, 2008. The following is a summary of the Committee's deliberations.

1. Transplant Tourism

a. Proposal for adding a removal code regarding transplant in another country

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. This data collection effort will enable the OPTN to more accurately quantify how many Americans travel to countries outside of the US for transplants. The Committee agreed that UNOS staff should pursue the addition of the following data field additions in Waitlist.

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]

The proposal removal code will be a new option in a list of removal codes that already exists in Waitlist. The sub-questions will be optional, i.e., not "required," data entry fields.

The Committee commented that many transplant centers would likely not remove candidates from the waiting list until they learn that candidates have actually received or planned to receive transplants overseas. The Committee asked UNOS staff to research the following: whether OPTN/UNOS policies necessitate removal of a candidate from the Waitlist due to transplant in another country. The Committee commented that if this concept is not in the policy language currently, then this language may need to be inserted to ensure collection of the removal data proposed above. The Committee commented that the policies that address removal of and re-transplant of candidates who await and receive transplants domestically should also apply to this population of candidates who receive transplants in another country.

Action Items:

- Add the proposed removal code and its sub-questions to Waitlist; and,
- Draft relevant policy language.

b. Follow-up form for patients who received transplants in another country, but are being medically followed in the United States

The Committee continued its discussion of developing a follow-up form that would track candidates who received transplants overseas, and are medically followed at transplant centers in the US.

UNOS staff commented that the OPTN/UNOS Policy Oversight Committee (POC) would need to review this proposal for a follow-up form, and that considering their opinions would be beneficial in the development of this follow-up form.

The Committee, however, suggested that the existing OPTN/UNOS follow-up forms could apply for this sub-population of candidates, and that a new follow-up form is not necessary. However, the transplant center would need to report that it is following a candidate who received a transplant in another country. The transplant center would also need to indicate in what country the candidate received the transplant. Otherwise, the center should follow the protocol for medical follow-up as it exists for a candidate who receives a transplant in the United States. The Committee suggested that this center reporting requirement – notify UNOS that it is following a candidate that received a transplant in another country – be included in the relevant OPTN/UNOS policy.

The Committee discussed the follow-up of recipients who were never placed on the Waitlist. UNOS staff commented that there already exist follow-up forms for such candidates. For example, there are some living donor cases that involve recipients who were never listed on the Waitlist. UNOS staff will explore the follow-up forms to determine which, if any, data elements may need to become “optional” fields with respect to data entry regarding recipients transplanted outside of the United States.

Action Items:

- Obtain input on this proposal from the POC; and
- Draft relevant policy language.

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

UNOS staff shared with the Committee the comments of the POC regarding Policy 6.0. The POC evaluated these policies for readability, goals, and objectives. The Committee reviewed the comments of the POC. The Committee did not have any feedback for the POC.

Action Item:

- UNOS staff will draft revisions to Policy 6.0, based on the discussions of the Committee in the 2007-2008 meetings and the comments from the POC.

3. Annual Goal: 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 Committee continued its discussion of this annual goal with invited guest, Mr. Joseph Ferreira. Mr. Ferreira is the Associate Director of Clinical Operations with the Life Alliance Organ Recovery Agency. The Committee discussed the need to provide clear guidance to the transplant community about the need to ensure the safety of imported organs; that ethical procurement practices, as sanctioned in the US, were applied in procuring the donor organs overseas; and that there are clear rules for the distribution of organs imported from another country. The Committee wishes to change the relevant policy language to address these three focus areas, especially given that there is an absence of organizations that certify internationally organ procurement organizations (OPO) or laboratories. The intent of this policy language change is to further ensure that organs imported to the United States comply with its laws, as well as current donation and transplantation practices.

Mr. Ferreira presented examples of how his OPO engages with foreign organizations that are considering exporting organs to his OPO. (The Life Alliance Organ Recovery Agency has imported organs from the Bahamas and Panama, and has a formal organ import agreement with the Bahamas.) The following is a list of practices that Mr. Ferreira's OPO routinely collects or engages in to ensure that the organs imported to this organization comply with US laws and medical practices. The Committee considered this list as what other OPOs engage in to ensure that their imported organs are procured legitimately and are medically suitable for transplant. The Committee suggested that UNOS staff include this list, or its derivative, in the revisions to the relevant policies.

- Evaluate brain death pronouncement guidelines. [How similar are these guidelines to that of the relevant US OPO?]
- Evaluate organ donor consent guidelines. [How similar are these guidelines to that of the relevant US OPO?]
- Ensure that the organ donor was not compensated for the donated organ(s).
- What type of credentialing for organ procurement programs exist in the given country?
- Is the foreign organization (lab or OPO) certified by a foreign association? Are these credentialing organizations comparable to what exist in the US?
- Is the relevant medical practice current, e.g., follows modern medical guidelines for managing the donor?
- Evaluate organ procurement policies and procedures of the foreign OPO. [How do these compare to those of the relevant US OPO and OPTN/UNOS policies?]
- Evaluate the donor serology and medical social history.
- Evaluate laws of the given country to determine that exporting an organ from that country for transplant is legal.

In addition to the list above, in the revised language, readers will be referred to Policy 6.4.4 (Ethical Practices). For policy monitoring purposes, the Committee commented that US OPOs should retain documentation that pertains to the above list.

Mr. Ferreira commented that OPOs wishing to develop a formal relationship with a foreign organization for the importation of organs (Policy 6.4.2) may wish to consider a site visit to the foreign organ procurement and laboratory organizations for more information about their practices. This site visit may yield additional information about the legitimacy of the foreign organizations.

Action Items:

- UNOS staff will draft revisions to the relevant policies.
- UNOS staff will distribute these revised policies during the June, 2008 public comment cycle.

4. Re-write of 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. The Committee discussed how the Committee could ensure that centers comply with this policy.

One alternative proposed was for centers to work with their OPO to develop a mutually-agreed upon communication protocol. Then, the given OPO Board could review these protocols for their completeness and appropriateness for their community. The strength of this protocol is that it would ensure that the communication plan was community-centered. The weakness of this alternative is that the Committee would not know whether the protocols were developed or learn the quality of these protocols.

Another alternative proposed was for the Committee to review all communication protocols. The Committee could request centers to submit their protocols one year after this revised policy is approved by Board. The strength of this proposal is that this review would enable the Committee to evaluate all proposals, and make recommendations to each center based on its intent for the policy. This proposal ensures that the Committee would be aware of all communication protocols developed nationwide. The weakness of this alternative is that it would place undue burden on the Committee. Further, in order to fully follow-through, the Committee would need to review protocols periodically. This micro-review by the Committee is not the Committee's intent for this policy revision.

After some discussion, the Committee proposed the following alternative: the Committee would review these communication protocols, but only from those transplant centers audited per Policy 6.3 (Audit). The Committee would not review these protocols during a special time-line; rather, the Committee would review this protocol for each center that exceeds the 5% non-resident alien transplant rate. [This request for documentation related Policy 6.2.5 has already been a part of the audit letter.] The strength of this alternative is that the Committee would evaluate protocols of only those centers with an apparent large non-resident alien candidate population, as evidenced by their greater than 5% non-resident alien transplant rate. The weakness of this alternative is that the Committee would not learn, systematically, what communication protocols are being developed and applied nationally. However, given that there is variability in what centers are audited annually, the Committee will review, over time, a large number of communication protocols.

UNOS staff will distribute the revised Policy 6.2.5 (see below) for public comment in June, 2008. The following draft of the revised language incorporates the Committee's evaluation alternative.

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 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 determine the frequency of and medium for the community dialogue, as well as the logistics for implementing this dialogue. The Ad Hoc International Relations Committee will evaluate the communication protocol for a center that exceeds the 5% non-resident alien transplant rate as outlined in Policy 6.3 (Audit).

Action Item:

- UNOS staff will draft the public comment document and share it with the Committee.

5. Review of Historical Data of Centers Receiving Audit Letters

At its last meeting, the Committee had requested historical non-resident alien transplant data for centers that exceeded the 5% non-resident alien transplant rate (Policy 6.3) in 2005 and 2006. On March 19, the Committee reviewed these data that spanned the years 1998 through 2007. While the Committee re-affirmed its decision from January 8 to distribute audit letters to these 6 centers, for one center, however, it voted to amend the number of letters it would send (3-yes, 0-no, 0-abstention).

This one center was to receive two letters: one letter to the multi-organ intestine program, and one letter to the pancreas program. The Committee commented that since pancreas is typically transplanted as part of a multi-organ intestine effort, a separate letter to this pancreas program does not seem fair. UNOS staff will make this adjustment.

The Committee will discuss the 2007 data at its next meeting.

The Committee also discussed the content of the audit letter. The Committee commented that the questions asked of the centers in the audit letter were still current and relevant for evaluating the justification provided by centers for their >5% non-resident alien transplant rate. The Committee suggested retention of the “non-US citizen” language and substitution of “DSA” for “OPO” in the question, “How many non-US citizen organ donors were procured during this time period in your OPO?” The Committee commented that changing “non-US citizen” to “non-resident alien” may present legal issues, and may threaten donation from and transplantation of non-resident aliens.

Action Items:

- UNOS staff will edit the audit letter as described above, and distribute to the 6 centers.
- UNOS staff will prepare the 2007 non-resident alien transplant data for discussion at the next Committee meeting.

Ad Hoc International Relations Committee	March 19, 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, M	At Large	
David R Grant, MD	At Large	
Marian A. O'Rourke, RN, CCTC	At Large	By phone
Myron E. Schwartz, MD	At Large	
Tatiana Alvarez, RN, BSN, CCTC	At Large	
Joseph Ferreira (Life Alliance Organ Recovery Agency)	Guest	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
David Clark	Support Staff	By phone
Stacey Burson	Support Staff	By phone