

OPTN/UNOS Ad Hoc International Relations Committee

SUMMARY

Action Items for Board Consideration

- None

Significant Items (Do Not Require Board Action)

- *Identify Scope of Transplant Tourism Practiced by Americans (Annual Goal)*
The Committee continues its efforts to capture the scope and public health impact of transplant tourism practiced by Americans. The Committee plans to add a waitlist removal code to more accurately ascertain the number of candidates removed from the waitlist, because they received transplants outside of the United States (US). The Committee will develop a follow-up form to gather information about American patients who travel outside of the country to receive transplants, but who are followed by US transplant centers. The Committee will compile an annotated bibliography of the literature on transplant tourism practiced by Americans. (Item 1, Page 3)
- *Strengthen Language in Relevant Organ Import Policies Regarding Safety of Organs and Legitimacy of Foreign Organizations Involved (Annual Goal)*
The Committee plans to modify the import policies to include language about ensuring the quality and safety of organs imported, and the legitimacy of the foreign organizations involved. The Committee will submit these modifications for public comment in 2008. (Item 2, Page 6)
- *Number of Organs Imported and Organs Exported (Annual Goal)*
The Committee continues to monitor organs imported from other countries, and organs exported from the US. Between January, 2002 and April, 2007, there were 231 organs exported from the nation. Of these, nearly all (95%) of the organs exported were thoracic (121 hearts; 99 lungs). Between January, 2002 and April, 2007, there were 38 organs imported from other countries. (Item 3, Page 7)
- *Modifications to Policy 6.2.5 (Community Participation)*
The Committee seeks to clarify the intent of this policy, and in particular, the phrase “mechanism for community participation.” The Committee will submit this modification for public comment in 2008. (Item 5, Page 8)
- *Programs that Transplanted More than 5% Non-Resident Alien Candidates in 2005 and 2006*
The Committee reviewed 2005 and 2006 data on the number of non-resident aliens transplanted in the US. As indicated in Policy 6.3 (Audit), the Committee voted to send letters to 6 programs that exceeded the transplant rate of 5%. (Item 6, Page 10)

This page is intentionally left blank.



**Report of the OPTN/UNOS Ad Hoc International Relations Committee to the
Board of Directors
February 20-21, 2008
Orlando, Florida**

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

The OPTN/UNOS Ad Hoc International Relations Committee met by telephone on August 4, 2006, August 7, 2007, September 28, 2007, October 11, 2007, and January 8, 2008. On September 28, 2007, the Committee completed its discussion of items on the August 7, 2007 agenda. The following is a summary of the Committee's deliberations:

1. Identify Scope of Transplant Tourism Practiced by Americans (Annual Goal)

On August 7, 2007, the Committee discussed the charge from Dr. Timothy Pruett, OPTN/UNOS President, to identify the number of Americans who travel outside of the US for transplants. The Committee considered possible methods for gathering this information. UNOS staff stated that a review of data collected during waitlist removal might provide some information. In the list of reasons for removing a candidate from the waitlist, there is an "other" category where data can be provided. Often, if the reason for removal is a transplant in another country, this reason is provided in this "other" category. The Committee also considered circulating a questionnaire to transplant centers to obtain information about candidates who travel outside of the country for transplants, and patients seeking post-transplant care after receiving transplants overseas.

The SRTR reported on a transplant tourism study it had presented at the 2007 American Transplant Congress. The SRTR reviewed the "other" OPTN data field referenced above. The SRTR sent a questionnaire to transplant centers identified from this field, as well as to those documenting waitlist removals where the corresponding transplant event could not be confirmed. The SRTR will share this abstract with the Committee at the next meeting.

The Committee also inquired about the possibility of requiring the candidate to state the country in which they were going to be transplanted. UNOS staff will research this possibility and provide an update at the next meeting. One Committee member suggested inviting Dr. Francis Delmonico (former OPTN/UNOS President) to discuss the global scope of transplant tourism. Dr. Delmonico is affiliated with the World Health Organization's Advisory for Human Transplantation.

UNOS staff stated that in June, 2007, the OPTN Board of Directors approved a statement on transplant tourism that included language about the medical community obligation to care for patients returning to the US after receiving transplants overseas. This statement's impact on the transplant community might facilitate future data collection on the number of American recipients who seek care in the US after receiving transplants overseas.

Action Items Resulting from the August 7, 2007 Meeting:

- UNOS staff will coordinate Dr. Delmonico's participation at the next Committee meeting.
- SRTR will share the ATC study with the Committee at the next Committee meeting.

On October 11, 2007, the Committee continued its discussion on tabulating the number of Americans who travel outside of the US for transplants. Dr. Francis Delmonico, former OPTN/UNOS President, provided information on the global prevalence and characteristics of transplant tourism.

Dr. Delmonico, citing an SRTR study, commented that in the past 20 years, there were several hundred Americans who left the United States to receive transplants overseas. Some of these transplants may have used organs that were procured ethically, but some have not. In China last year, there were 11,000 transplants performed, and a majority of these organs were recovered from executed prisoners. Also, a majority of these 11,000 recipients were tourists who had traveled to China for transplants. The World Health Organization and the Transplantation Society condemns the transplantation of organs recovered from executed prisoners.

Buying and selling of organs occur in India, Philippines, and Pakistan. Americans are visiting these countries as well to receive transplants. In the US, it is illegal to buy or sell organs.

The SRTR provided a summary of a poster it had presented at the 2007 American Transplant Congress (Exhibit A). The study, entitled “Transplant Tourism among Patients Removed from the US Kidney Transplant Waiting List,” will be a chapter in the OPTN/SRTR Annual Report. The data collection period for this study was 1986-2006. The study used OPTN data.

According to this SRTR study, in the past 20 years, there were 373 Americans who traveled overseas for a kidney transplant. About half of the kidney recipients were Asian-Americans. Further, many of these Asian-Americans traveled to China for transplants. Americans also traveled to India, Philippines and other countries for transplants.

The SRTR study may under-represent the actual number of Americans who traveled overseas in the past 20 years to receive transplants. Current OPTN methods for gathering data on overseas transplants are not useful for making generalizations about the practice of transplant tourism by Americans. Currently, information about an overseas transplant is not explicitly collected by the OPTN. UNOS staff commented that the OPTN only collects data on candidates who register to be on the transplant waitlist. As a result, these data don’t take into account those candidates who never register to be on the waiting list, and instead, travel outside of the country for transplants. (When a paper of this study is complete, SRTR will share it with the Committee.)

Dr. Delmonico reported that the Ministry of Health of China declared recently that only Chinese citizens can receive transplants in China. There are, however, several Chinese military hospitals that are not governed by this Ministry of Health. It is likely that in these military hospitals, foreigners may continue to receive transplants.

Americans are also likely to visit Manila, Philippines for transplants. There are several hospitals in Manila that cater to foreigners traveling overseas for transplants as well as other medical treatments. Further, the government of the Philippines approved another hospital to provide care to foreign patients traveling overseas for medical care. The World Health Organization is researching the demographics of transplant candidates visiting Manila for transplants.

Dr. Delmonico commented that in the weeks following this Committee meeting, he would be traveling to various countries to continue exploring the global scope of transplant tourism. The Committee requested that he present his findings at the next Committee meeting.

Based on the SRTR’s research and Dr. Delmonico’s presentation, the Committee agreed that the practice of transplant tourism by Americans is likely to be far more prevalent than the 373 occurrences identified in the SRTR study. The Committee discussed what information the Centers for Medicare and Medicaid Services (CMS) could provide for quantifying the scope of transplant tourism. The HRSA representative reported that CMS does not pay for medications when transplants

are performed outside of the country. The Committee will ask CMS how often it compensated or denied compensation to patients for transplant medications. Some of these denials could be due to transplants received outside of the US.

The HRSA representative suggested that the Committee also describe the public health concerns (such as disease transmission) that exist with transplant tourism. The Committee agreed to describe the potential public health impact of Americans practicing transplant tourism.

The Committee will also develop and implement a survey to learn how many patients who received transplants overseas seek medical follow-up at US transplant centers. The survey could be distributed to transplant programs, transplant physicians represented by medical societies, and perhaps the local health departments. The HRSA representative cautioned that HIPAA regulations may prevent health care providers from releasing this information. The Committee will present its data collection plan to document the actual practice of transplant tourism, as well as relevant data, to the Board of Directors in February, 2008.

Action Items Resulting from the October 11, 2007 Meeting:

- UNOS staff will develop a questionnaire to assess the number of patients who obtained transplants overseas now seek medical follow-up at private and public health sectors.
- UNOS staff will research the number of CMS denials of transplant medication compensation requests.
- UNOS staff will research the HIPAA regulations that may prevent requesting medical follow-up information.
- UNOS staff will invite Dr. Delmonico to the next Committee meeting.

On January 8, 2008, the OPTN/UNOS President, Dr. Tim Pruett, recommended 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 transplants overseas, and who receive follow-up medical care at OPTN member transplant 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 patients who receive transplants overseas and visit medical professionals who are not in the OPTN system.

The Committee discussed the addition of a removal code and voted favorably to advance this project: 3-Yes, 0-No, 0-Abstention. At its next meeting, the Committee will discuss the overseas transplant follow-up form.

Action Items Resulting from the January 8, 2008 Meeting:

- 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.

2. Strengthen Language in Relevant Organ Import Policies Regarding Safety of Organs and Legitimacy of Foreign Organizations Involved (Annual Goal)

On August 7, 2007, the Committee decided that it would streamline the organ import process by focusing on the following issues: 1) legitimacy of the foreign organization offering the organ; 2) testing/safety of the foreign organ being offered; 3) rules of organ distribution between countries; and, 4) explore an exemption to Policy 6.3.

The Committee decided that for items 1-3 above, it will review existing, relevant OPTN policies to determine whether the language needs to be strengthened to meet these goals. The intent of these three goals is to ensure that the foreign organizations offering the organs are legitimate, and that the organs offered are medically safe for transplantation. These topics have been discussed by the Committee in the past. UNOS staff will research whether the foreign organs offered to an organ procurement organization (OPO) in the US are distributed using a national or local match-run.

The Committee will explore in the next year an exemption to Policy 6.3 that would accommodate the following scenario: If organs are offered to a US transplant center X from country Y, then the US transplant center X would transplant a non-resident alien recipient who is a national of country Y. A transplant event resulting from this reciprocal offer from the US transplant center X would be exempt from the review outlined in Policy 6.3 (Audit). In the next year, the Committee will review evidence that would support or not support this concept.

Action Items Resulting from the August 7, 2007 Meeting:

- UNOS staff will forward this annual goal to Dr. Pruett.
- UNOS staff will research the information relevant for accomplishing this annual goal.

On January 8, 2008, the Committee continued its review of organ import policies to strengthen language regarding organ safety, and the legitimacy of foreign organizations making organ offers. The Committee inquired about measures used internationally to recognize organ procurement organizations. If there is an international registry of organ procurement organizations, then a foreign OPO registered with this body could be considered legitimate 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 organizations. There are international standards for laboratories. If a foreign laboratory is in compliance with these international standards, then results of organs tested at this laboratory could be considered legitimate. As a precaution, the US OPO importing the organ could perform additional lab tests related to organ safety.

UNOS staff stated that Policies 6.4.2 (Developmental Protocols in International Organ Exchange) and 6.4.2.1 could incorporate information about organ safety, and legitimacy of the foreign organizations involved in offering organs. These policies could also include information about preventing transmission of donor-related diseases. UNOS staff also commented that the body of policies categorized under 6.0 could also improve in readability. The Committee decided that the “rules of distribution” are well-defined in Policy 6.4.2.1.

The Committee emphasized the need to strengthen these organ import policies. The Committee Chair stated that in his conversations with Dr. Frank Delmonico, former OPTN/UNOS President, Dr. Delmonico supported the Committee’s efforts to strengthen these policies. The Committee encouraged UNOS staff to revise language in the relevant policies, and present a draft at the next meeting. The Committee encouraged revisions that would improve the readability of these policies. The Committee intends to submit these policy revisions for public comment in June, 2008.

Action Items Resulting from the January 8, 2008 Meeting:

- 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. Number of Organs Imported and Organs Exported (Annual Goal)

On August 4, 2006, the Committee reviewed data regarding the number of donor organs imported from another country and organs exported from the US (Exhibit B). These data were from January, 1998 to March, 2006. The data indicated that the numbers of organs imported from outside of the US in 2005 were approximately the same as in the previous year. The number of organs exported from the US in 2005 increased from the previous year. It was noted that in 2004 and 2005, there weren't any organs imported from the Bahamas; however, a member recalled imports occurring in those time frames. The Committee requested further review of OPO records regarding organ imports from the Bahamas. It was also noted that the only organs exported were hearts and lungs. A request was made by the Committee to review those organs recovered for transplant but exported out of the US. Historically, a large number of these organs were from very young pediatric donors, or from hospitals in Alaska. The Committee expressed interest in the recovery patterns of the other organs for this same donor population. The Committee wanted to review donors with at least one organ recovered for transplant and exported out of the US, and review data on the disposition of the other organs; this analysis should be stratified by donor age and the area of the country where the organs were recovered.

On August 7, 2007, the Committee requested a review of the number of organs exported from the US and imported from other countries. UNOS staff will provide the Committee, at the next full meeting, the number of organs imported and exported in 2006 and 2007. This data request is a Committee charge from the OPTN/UNOS President, Dr. Timothy Pruett.

Action Item Resulting from the August 7, 2007 Meeting:

- At the next meeting, UNOS staff will provide data on the number of organs imported to and exported from the US.

On September 28, 2008, UNOS staff reported that between January, 2002 and April, 2007, there were 231 organs exported from the nation (Exhibit C). Of these, nearly all (95%) of the organs exported were thoracic (121 hearts; 99 lungs). A high percentage of these thoracic organs were from pediatric donors. Many of these organs were recovered in Alaska, where the cold-time limitations necessitated exports to Canada. Regions 5 and 10 were the primary exporters of thoracic organs. Exported hearts were primarily from donors less than 6 years of age. The rate of organs transplanted per donor, from whom a heart was exported, was 3.9. In this group, there were 6 donors where 6 organs were transplanted. There were also 7 cases where the heart was not ultimately transplanted.

Region 5 was the primary exporter of lungs. Regions 2, 10, 6, and 9 also exported lungs. The lungs were from primarily adult donors.

Canada was the recipient of all the exported organs in this analysis.

Of the non-thoracic organs exported, there were 5 livers exported between January, 2002 and April, 2007. Of these, 4 were exported in 2006. Also, 4 of the 5 livers were recovered from donors less than 6 years of age. Various regions exported the non-thoracic organs.

The number of organs from the US might reflect the aggressive placement efforts of the OPOs

recovering these organs.

4. Maintain the Public's Trust in the Organ Allocation System (Annual Goal)

On August 7, 2007, the Committee determined that it will maintain the public's trust in the organ allocation system by investigating questionable allocation events, and maintaining complete transparency in the organ transplantation process.

The Committee discussed that this goal is really its "modus operandi," and that to continue to achieve this goal, it is important to also ensure the accuracy of the data presented to the community.

Action Item Resulting from the August 7, 2007 Meeting:

- UNOS staff will forward this annual goal to Dr. Timothy Pruett, OPTN/UNOS President.

5. Clarification of Policy 6.2.5 (Community Participation)

On September 28, 2007, the Committee discussed a request from a transplant community member: clarify the intent of the phrase "mechanism for community participation" in Policy 6.2.5 (see below).

6.2.5 Community Participation. Each member center which lists non-resident aliens on its Waiting List should establish a mechanism for community participation and review of its candidate acceptance criteria.

The Committee discussed the possible interpretations of this policy. Within the Committee, there were some differing interpretations of this phrase. One member considered this language as encouragement for initiating dialogue about improving transplantation practices in the communities of origin of non-resident alien transplant candidates. If these candidates are coming to the US for transplant because they are not being accepted for this procedure in their home countries, then one effort of this dialogue would be to broaden the transplant acceptance criteria in the given country.

Another member interpreted "mechanism for community participation" as the transplant center's opportunity to engage the local community (public, not transplant professional) in a dialogue about its candidate acceptance practices as they apply to non-resident aliens.

UNOS staff stated that the original intent of this policy was to generate transparency of and public participation in the OPTN process. In the past, there were discussions about developing separate lists for separate citizen classes, and the community decided that one waiting list for all citizen groups would be best. Within this one list, there exists a threshold rate associated with the number of non-resident aliens a center may transplant annually without a Committee review (Policy 6.3).

The Committee discussed two approaches for clarifying the intent of "mechanism for community participation". One proposed method was to query the OPTN community on its current understanding of this phrase. Another method was to provide a definition, stemming from within the Committee, of "mechanism for community participation." The Committee preferred the latter approach. UNOS staff will draft this language for review at a future meeting. This definition should convey that the intent of the dialogue is to communicate how and why transplant center candidate acceptance practices apply to non-resident aliens. This language should include an example of how to implement the policy.

Action Item Resulting from the September 28, 2007 Meeting:

- UNOS staff will draft the revisions and present it at a future Committee meeting.

On January 8, 2008, the Committee continued its discussion about clarifying Policy 6.2.5. UNOS staff presented a first draft of the revised policy language (shown below). These revisions incorporated the Committee's discussion about the policy on August/September, 2007.

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," for clarity and 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 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 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 Item Resulting from the January 8, 2008 Meeting:

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

6. Programs that Transplanted More than 5% Non-Resident Alien Candidates in 2005 and 2006

On August 4, 2006, the Committee reviewed data on the citizenship of recipients of deceased donor transplants in the years 2004 and 2005 (Exhibit D). The Committee identified programs reporting a non-resident alien transplant rate exceeding 5% of the annual total transplants for two consecutive years. The Committee excluded from its review programs that the 5% rate by performing only one transplant. One program was identified as exceeding the 5% rate between January, 2004 and December, 2004, and again between January, 2005 and December, 2005.

As written in Policy 6.3 (Audit) below, on January 8, 2008, the Committee reviewed the annual rates of non-resident alien transplants performed in 2005 and 2006.

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 (Exhibit E). (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. The analysis presented detailed data for these 45 programs. (The OPTN Transplant Candidate Registration (TCR) form collects citizenship information about each recipient.)

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

Of the 871 programs examined in this analysis, 45 (5%) programs performed non-resident alien deceased donor transplants at a rate higher than 5% during 2005 or 2006. 14 (1.6%) of these 45 programs exceeded the 5% rate by performing at least two non-resident alien transplants in one calendar year. 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 audit programs that exceeded the 5% rate as a result of one transplant event. The Committee sought a pattern in programs exceeding the 5% rate. The Committee decided to 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 greater than 5% non-resident alien transplant rate. The Committee inquired 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 transplant statistics. The Chair abstained from voting on the decision to send any letters to this center. So, in this case, the voting was 2-Yes, 0-No, and 1-Abstention 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 do not respond to the Committee's audit. Exceeding the 5% rate, however, is not a violation of policy. Also, Policy 6.5 (Violation of Policies) includes the phrase "persistent violations." UNOS staff commented that "persistent" may be too vague to clearly identify a center that has violated Policy 6.3, and requested that the Committee consider clarifying this phrase. The Committee requested that UNOS staff share this discussion with the other members not in attendance. The Committee asked these members to comment whether they support or oppose the audit votes.

Action Items Resulting from the January 8, 2008 Meeting:

- 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.

7. Committee's Role with Policy 6.3 (Audit)

On October 11, 2007, UNOS staff reported that the Membership and Professional Standards Committee (MPSC) planned to discuss Policy 6.3 and determine whether the program audit should be its responsibility.

This program audit is a core effort of the Committee. The Committee offered that in the future, it could forward to the MPSC the following: data on transplant programs exceeding the 5% rate, the Committee's deliberations on these data, and any resulting actions. Currently, the Committee only communicates to the MPSC those programs that violate Policy 6.3. These violations, however, occur infrequently. With the current suggestion, the Committee would share non-resident alien transplant data with the MPSC even in the absence of any policy violation.

During this meeting, the Committee also decided to review non-resident transplant data annually. The Committee had previously reviewed these data every two years, and it had last reviewed these data on August, 2006. The Committee will review data from 2005 and 2006 at its next meeting.

Action Items Resulting from the October 11, 2007 Meeting:

- UNOS staff will forward to the MPSC the Committee's suggestion about sharing non-resident alien transplant data sooner than when policy violations occur.
- UNOS staff will present 2005 and 2006 non-resident alien transplant data at the next Committee meeting.

On January 8, 2008, UNOS staff reported that the MPSC would not be requesting the Committee to share the non-resident alien transplant center data. Reviewing these data remains the responsibility of the Committee, not the MPSC. The Committee acknowledged this request.

8. Pediatric Resident and Non-Resident Alien Donors and Transplant Recipients

On August 4, 2006, the Committee discussed a memorandum it had received from the OPTN/UNOS Pediatric Transplantation Committee. In the memorandum, the Pediatric Transplantation Committee requested guidance on issues involved in the transplantation of illegal aliens. The Pediatric Committee commented that listing and transplantation of illegal alien candidates residing in the United States is occurring with increasing frequency. The practice of accepting these candidates for transplantation is highly variable among programs. Some centers turn these patients away due to their illegal status and/or lack of insurance, while others may list and eventually transplant these candidates using charity funds from outside sources or funding built into the hospital budget. As a general principle, members of the Committee do not believe that the immigration status of individual patients should play a part in organ allocation policies. The Committee felt that the issues raised by the Pediatric Committee regarding the transplantation of illegal aliens were similar to issues that apply to any patient without insurance. The Committee opined that centers need to determine whether they are willing to accept these patients regardless of their immigration status. Further, if a center accepts these patients, then the center should treat these patients like any other. The Committee wanted to know if the number of these transplants has increased over time, the ages of these recipients, and if the number of donors recovered from this same group has changed over time. The Committee will provide a summary of its discussion regarding the issues involved with accepting illegal aliens for transplant to the Pediatric Committee.

On September 28, 2007, UNOS staff reported that limited data are collected on donor and transplant recipient citizenship status. OPTN does not collect data on a donor's or candidate's legal residence status. The OPTN has the following information about the donor's or candidate's citizenship status: US citizen; non-US citizen, resident alien; and, non-US citizen, non-resident alien.

UNOS staff reported on its analysis of the transplants performed and deceased donors recovered, by the three citizenship groupings. The analysis incorporated data collected during 2002-2006. Of the total number of non-resident alien transplant recipients during 2002-2006, a higher percentage of them were pediatric patients. The age distributions in the U.S. citizen and resident alien transplants show less variation.

With respect to donation, overall, the number of non-US citizen donors has decreased over the last five years. The most substantial decrease is in the number of resident alien donors, which has decreased from a high of 233 in 2003 to 79 during 2006. The number of non-resident alien donors has remained more stable over the past five years, with a high of 56 in 2003 and a low of 43 in 2006. Among the US citizen deceased donor population, during this period, the pediatric age-group comprised over 13% of the total. However, this proportion is much smaller for the resident and non-resident alien donors, where pediatric donors comprise 5.4% and 6.0% of the total, respectively.

This analysis could not address data by a candidate's legal or illegal status, as requested by the Pediatric Committee. These legal data are not collected currently. Collecting this information in the future, however, may have unintended consequences in the area of donation advocacy. Even if the legal status could be collected, the accuracy of the collected information may be compromised.

Action Item Resulting from the September 28, 2007 Meeting:

- UNOS staff will forward these data, as well as the Committee's discussion of them, to the Pediatric Committee.

9. Discussion of Developmental Protocols in International Organ Exchange

On August 4, 2006, the Committee discussed possible ways to streamline the process for organ procurement agencies to establish relationships with centers outside of the US for the purposes of organ exchange. Pursuant to Policy 6.4.3 (Ad Hoc Organ Exchange), a formalized agreement must be made if any UNOS member executes more than six exchanges with any foreign program(s). This policy stipulates that an international organ exchange protocol must be approved by the Committee and Board of Directors, reviewed at least annually by the Committee, and cannot exceed two years in duration. A Memorandum of Understanding was developed by the Life Alliance Organ Recovery Agency for use with its relationships with the Bahamas, and also utilized by the New England Organ Bank in its relationship with Bermuda. The Committee reviewed a draft of a Memorandum of Understanding which could be used as a template by other OPOs wanting to establish organ exchange relationships with centers outside the US. The revised document will focus on the items that must be in a protocol. The document will be presented to the Committee at its next meeting.

10. Gift of Life of Michigan

For its August 7, 2007 meeting, the Committee received a request from UNOS staff to discuss Gift of Life of Michigan's organ export practice. On September 28, 2007, the Committee acknowledged this request, but did not discuss it. UNOS staff advised the Committee that this organ export practice needed to be considered by organ allocation committees as an alternative allocation system. Essentially, the Gift of Life of Michigan may not be exhausting the national waitlist before exporting organs to Canada. This practice may not be consistent with Policy 6.4. A discussion of this topic did not fall within the purview of the Committee.

Action Item Resulting from the August 7, 2007 Meeting:

- UNOS staff will convey to the Gift of Life of Michigan that the Committee did not discuss their organ export practice.

11. Ethics of Disclosing Donor-Donee Relationships

On September 28, 2007, the Committee discussed the following question that it had received from an individual residing outside of the United States:

[...] "I request your opinion on one remedy that we are considering to curb illegal kidney retrieval from live unrelated donors which is being opposed by some doctors as infringing "medical ethics". We wish to publish names / addresses of prospective donors and intended donees in newspapers and enforce a stipulated waiting period before scheduling surgery. It is our contention that this would give civil society a reasonable chance to uncover fake "affection" and illegal payments. " [...]

The Committee determined that the ethical question described above is more appropriate for consideration by the OPTN/UNOS Ethics Committee. The Committee did not discuss this issue, and will forward this issue to the Ethics Committee.

Action Item Resulting from the September 28, 2007 Meeting:

- UNOS staff will forward the ethical question described above to the Ethics Committee.

12. Meeting the HHS Program Goals

On August 4, 2006, UNOS staff provided the Committee with background and data regarding the HHS Program Goals. These Program Goals are now part of the new OPTN contract. These goals were established to increase the number of donors, transplants, and kidney transplant life years gained while decreasing OPTN costs per transplant. Similar goals for life years gained will be developed for other organs as well. The Committee reviewed a series of slides depicting actual donor and transplant numbers, as compared to the Program Goals for future years. The Committee noted that their work with forming relationships with other countries, such as Massachusetts with Bermuda and Miami with Bahamas and St. Croix, could aid in this effort by leading the way for other donor service areas to procure organs from foreign donors in the U.S. and import organs from other countries.

On August 7, 2007, UNOS staff updated the Committee on the efforts of the OPTN, in 2006, to achieve the HHS Program Goals. The intent of the HHS goals is to increase the number of donors, organs transplanted, and organs transplanted per donor. Each year since 2004, the OPTN has met the goal for the total number of non-DCD deceased donors. In 2006, the OPTN exceeded its goal. The OPTN did not meet its goal for the total number of DCD donors, but it did experience a substantial increase in the number of DCD donors. Reaching this goal would have required an increase of 42% from the 2005 number. The national rate of organs transplanted per non-DCD donor in 2006 was 3.13, lower than the goal of 3.44. However, when only considering standard criteria non-DCD donors, the national rate was 3.44; the rate for expanded criteria donors was much lower. The OPTN did not meet the goal of 2.33 for organs transplanted per DCD donor. The OPTN's rate was 2.11, but there were some donation service areas that surpassed the 2.33 goal.

13. Review of Public Comment Proposals

The Committee discussed the following four public comment proposals on August 7, 2007.

Proposed Modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation

Since the scope of this proposal falls outside of its purview, the Committee submitted a "No Comment" as feedback to the MPSC and Living Donor Committee (4-No Comment; 0-Support; 0-Oppose; 0-Abstain).

Proposed Modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Living Donor Liver Transplants (Membership and Professional Standards and Living Donor Committees)

Since the scope of this proposal falls outside of its purview, the Committee submitted a "No Comment" as feedback to the MPSC and Living Donor Committee (4-No Comment; 0-Support; 0-Oppose; 0-Abstain).

Guidelines for the Medical Evaluation of Living Kidney Donors (Living Donor Committee)

The Committee "Abstained" from making any supporting or opposing comments (0-Support; 0-Oppose; 4-Abstain). The Committee, however, did provide the following suggestions, and would like to see these incorporated into the current proposal:

- These consent guidelines that pertain to living donors who are US citizens should also pertain to foreign nationals who come into the United States and are accepted as living donors.

- US transplant centers that perform transplants from living donors who are foreign-nationals should have a mechanism in place to follow-up and evaluate this living donor, in the same way they would for the living donor who is a US citizen.

Guidelines for the Consent of Living Donors (Living Donor Committee)

The Committee “Abstained” from making any supporting or opposing comments (0-Support; 0-Oppose; 4-Abstain). The Committee, however, did provide the following suggestion, and would like to see this incorporated into the current proposal:

- These consent guidelines that pertain to living donors who are US citizens should also pertain to foreign nationals who come into the United States and are accepted as living donors.

Action Item Resulting from the August 7, 2007 Meeting:

- UNOS staff will forward the Committee’s discussion and vote on the proposals above to the relevant sponsoring Committee’s liaison.

The Committee discussed the following public comment proposal on October 11, 2007.

Proposed Modification to the OPTN Bylaws, Appendix B, Transplant Hospitals; Section B. Survival Rates; and Section C “Inactive Membership Status”; and Attachment I, Section II, “Inactive Program Status”; and to the UNOS Bylaws, Attachment I, Section II “Inactive Program Status” and Attachment II, Section XIII, C, (10) “Survival Rates.” (Membership and Professional Standards Committee)

The Committee inquired if other Committees had any concerns with the proposal. UNOS staff commented that the Thoracic Organ Transplantation Committee voted to support the proposal, but sought clarification about which state’s statutes governed the summary referenced in the proposal. The Ad Hoc International Relations Committee also sought assurance that the medical peer review laws protected these informal discussions, including related summaries and conclusions.

Since the Committee’s teleconference on October 11, 2007 did not have a quorum, the Committee could not vote on this proposal. The Committee asked that UNOS staff obtain votes on this proposal electronically.

Action Items Resulting from the October 11, 2007 Meeting:

- UNOS staff will survey all Committee members to obtain their votes on this MPSC bylaw proposal, where quorum could be achieved.
- UNOS staff will forward to the MPSC liaison the Committee’s comments and votes on the proposal.

14. Board Meeting Committee Report

On January 8, 2008, the Committee discussed its report to the Board of Directors on February 21, 2008. Dr. Tzakis will present a report of 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.

Action Item Resulting from the January 8, 2008 Meeting:

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

Ad Hoc International Relations Committee	August 4, 2006 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	
Marian A. O'Rourke, RN, CCTC	At Large	
Myron E. Schwartz, M	At Large	
Nancy Carothers, RN	Ex Officio – HRSA	By phone
Jade Perdue	Ex Officio – HRSA	
Amy Bogard	Committee Liaison	By phone
Doug Heiney	Committee Liaison	By phone
Sarah Taranto	Support Staff	By phone
Courtney Bland	Support Staff	By phone

Ad Hoc International Relations Committee	August 7, 2007 Teleconference and Live Meeting (Discussed Remaining Agenda Items on September 28, 2007)	
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	By phone
Myron E. Schwartz, MD	At Large	
Tatiana Alvarez, RN, BSN, CCTC	At Large	
Nancy Carothers, RN	Ex Officio – HRSA	By phone
Jade Perdue	Ex Officio – HRSA	
Diane Steffick	SRTR Liaison	By phone
Vipra Ghimire	Committee Liaison	By phone
Doug Heiney	Committee Liaison	By phone
Sarah Taranto	Support Staff	By phone
Judy Martin	Support Staff	By phone
Stacey Burson	Support Staff	By phone
Chrystal Oley-Graybill	Support Staff	By phone
Catherine Monstello	Support Staff	By phone

Ad Hoc International Relations Committee	September 28, 2007 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	
Marian A. O'Rourke, RN, CCTC	At Large	By phone
Myron E. Schwartz, MD	At Large	
Tatiana Alvarez, RN, BSN, CCTC	At Large	By phone
Nancy Carothers, RN	Ex Officio – HRSA	By phone
Diane Steffick	SRTR Liaison	By phone
Vipra Ghimire	Committee Liaison	By phone
Doug Heiney	Committee Liaison	By phone
Sarah Taranto	Support Staff	By phone
Judy Martin	Support Staff	By phone
Stacey Burson	Support Staff	By phone

Ad Hoc International Relations Committee	October 11, 2007 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	
Marian A. O'Rourke, RN, CCTC	At Large	
Myron E. Schwartz, MD	At Large	
Tatiana Alvarez, RN, BSN, CCTC	At Large	By phone
Francis L. Delmonico, MD	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
Stacey Burson	Support Staff	By phone
Catherine Monstello	Support Staff	By phone

Ad Hoc International Relations Committee	January 8, 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	
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