

**Report of the Meeting of  
the Ad Hoc International Relations Committee**

**Chair – Gloria Garcia Bohrer  
Vice-Chair – Gabriel Danovitch, MD**

**April 28, 2010**

On April 28, 2010, the Ad Hoc International Relations Committee (Committee) met by telephone and Internet. The following pages provide a summary of the Committee's deliberations.

**Policy 6.1.1 (Non-Resident Alien): What are the next steps in modifying this policy?**

On April 19, 2010, the Executive Committee did not review the Committee's arguments for and against the proposed modifications to Policy 6.1.1 (Exhibit 1). The Committee discussed whether how best to proceed with the proposed policy language modifications. The Committee commented that advice from UNOS General Counsel would be necessary to avoid any legal implications of proceeding with the policy modification as previously discussed.

*Current Policy 6.1.1*

6.1.1 Non-Resident Alien. A non-resident alien is an individual granted permission by the United States Government to enter the United States on a temporary basis as a non-immigrant alien for purposes which include tourism, business, education, medical care, or temporary employment.

*Previously Proposed Modifications to Policy 6.1.1*

- Alternative 1  
6.1.1 Non-Resident Alien. A non-resident alien is an individual ~~granted permission by the United States Government to enter~~ residing in the United States on a temporary basis as a non-immigrant alien ~~for purposes which include tourism, business, education, medical care, or temporary employment.~~
  
- Alternative 2  
6.1.1 Non-Resident Alien. ~~An non-resident alien is an individual granted permission by~~ who is not a resident of the United States Government, according to the said government's definition, is a non-resident alien to enter the United States on a temporary basis as a non-immigrant alien for purposes which include tourism, business, education, medical care, or temporary employment.

The Committee queried the rationale for asking a candidate's or donor's citizenship status for the purposes of organ donation and transplantation. The collection of such data may place a transplant program in a "gatekeeper" role to determine, based on citizenship status, provision of clinical services. Further, the definition of non-resident alien appears to imply that transplant programs do not have a choice in choosing which patients to treat, i.e., the programs must only list candidates who are lawfully admitted to reside in the United States.

Policy 6.1.1 exists for the purposes of reporting citizenship status in UNet<sup>SM</sup>, and not for the purposes of guiding clinical practice of transplant programs. In fact, a transplant program has the choice to select which candidate, regardless of citizenship, to list for transplantation. Neither UNOS nor its

policies interfere with this center-specific decision. Indeed, Policy 6.2.1 (Nondiscrimination/Organ Allocation) states that once listed, a candidate that meets the non-resident alien definition must be treated the same as a resident or an American citizen. The UNet<sup>SM</sup> match-run page that identifies candidates eligible to receive a given deceased donor organ does not identify these individuals' citizenship status.

6.2.1 Nondiscrimination/Organ Allocation. Selection, from the Waiting List, of non-resident alien candidates for transplantation shall be based on the same allocation policies (Section 3.0) mandated by the Board of Directors for selection of domestic candidates. Such selection shall not be influenced by favoritism or discrimination based on political influence, national origin, race, sex, religion or financial status.

The transplant program decides if it wants to treat documented and undocumented individuals differently. One transplant program may want to only list for transplant individuals who have documentation to reside in the United States; and another transplant program may choose to list an individual for transplant, regardless of the person's immigration status. OPTN/UNOS policies are silent intentionally on organ allocation to undocumented individuals. Were the OPTN/UNOS to assert a position in policy, then some transplant programs, depending on their state laws, may not be able to comply with the OPTN/UNOS policy.

A Committee member commented that Policy 6.2.1 references those who meet the definition in Policy 6.1.1. So, excluding the undocumented candidates in Policy 6.1.1 means that these candidates are not protected by non nondiscrimination language in 6.2.1. While this interpretation is correct, UNOS staff commented that OPTN/UNOS stating a position on organ allocation to undocumented candidates would generate significant political commentary – favorable and unfavorable. In the late 1980s, when the transplant community considered the development of two waiting lists for transplantation – one for the American citizenry and another for the non-residents – the group did not broach candidates who may not have documentation to reside in the United States. Once the transplant community decided that there would be only one waiting list for transplantation, the nondiscrimination policy protected non-citizen candidates (or, non-resident candidates) from differential treatment for the purposes of organ allocation.

UNOS staff stated that historically, the organization has asserted that there is no prohibition against the transplantation of candidates who do not have documentation to reside in the United States. However, given that the definition of non-resident alien appears to have differing interpretations in the transplant community, particularly in the area of listing undocumented candidates for transplantation, it appears necessary to clarify the non-resident alien construct and its application in policy. However, staff sought clarification from the Committee on which policy problem to resolve: expansion of the nondiscrimination policy to include candidates who are undocumented; or clear language on the permissibility of listing and transplanting undocumented candidates. UNOS staff again clarified that while Policies 6.1.1 and 6.2.1 do not mention undocumented individuals, it is the transplant program's decision to list candidates for transplantation, regardless of immigration status. Further, given the current national discussions occurring about undocumented individuals, the Committee may want to consider remaining silent on this topic until decisions are made on the federal level.

The Committee, satisfied with the counsel provided by UNOS staff, discussed various policy alternatives, and will continue to do so at its next meeting. Some alternatives discussed were: non-resident alien definition resides only in UNet<sup>SM</sup>; and Policy 6.3 (Audit) could state that the >5% guideline applies to transplantation of all candidates who are not residents of the United States. The following is the current language in Policy 6.3:

6.3 AUDIT. 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.

Revising the language in Policy 6.3 as shown below may refocus the Policy 6.0 (Transplantation of Non-Resident Aliens) on people who travel to the United States for transplantation versus the argument on the transplantation of undocumented candidates. This refocus would be in compliance with the original intent of Policy 6.1.1, 6.2.1, and 6.3.

6.3 AUDIT. 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 candidates who are not residents of the United States ~~non-resident aliens~~. The Committee will review the activities of each member transplant center where such non-resident alien recipients constitute more than 5% of recipients of any particular type of deceased donor organ. At centers where non-resident alien transplant recipients who are not residents of the United States constitute more than 5% of recipients of any particular organ type, circumstances underlying the transplants for non-resident aliens these recipients will be reviewed by the Committee. Special consideration will be given to programs served by OPOs with non-resident alien organ donors who are not residents of the United States.

The above modifications to Policy 6.3 are draft and merely conceptual, but the Committee favored this alternative. UNOS staff will need to evaluate Policy 6.0 in its entirety for related revisions. The Committee tasked UNOS staff to start writing a draft of the policy proposal that would clarify the non-resident alien definition so that it better matched the policy's original intent.

### **Review of Responses to the AHIRC's Audit of Programs that Exceeded the >5% Non-Resident Alien Transplant Rate in 2008**

The Committee reviewed responses to its audits from the following three centers:

- Center 30659D (Liver Program)
- Center 15222D (Intestine and Liver Programs)
- Center 15867D (Kidney Program)

During the review of center #15222D, UNOS staff commented that the Committee twice audited this center's intestine program's 2007 non-resident alien transplant rate. The two separate audits occurred due to a change in the Committee's auditing schedule. In 2008, the Committee decided to review non-resident transplant rates annually. Previous to 2008, the Committee had reviewed non-resident alien transplant rates every two years. However, the Committee maintained its following methodology: 1) audit only programs that exceed the 5% rate for two consecutive years, including the year under review; and 2) audit only programs that exceed the 5% rate due to two or more transplants.

In 2008, the Committee sent center #15222D an audit letter for exceeding the 5% non-resident alien intestine transplant rate in 2006 and 2007. When the Committee reviewed non-resident alien

transplant rates in 2009 for the 2008 calendar year, it decided to send this same center's intestine program an audit letter for exceeding the non-resident alien transplant rate of 5% in 2007 and 2008. So, this center's intestine program received two audit letters, separately, but for the same calendar year – 2007. UNOS staff recognized this mistake only after distributing the audit letters for 2008. UNOS staff advised this center's intestine program to submit a response to the audit only for the calendar year 2008. UNOS staff had included in the Committee packet for the April 28, 2010 meeting this intestine program's 2007 response. The Committee's had voted in favor of this intestine program's response for exceeding the non-resident alien transplant rate in the 2007 calendar year.

On April 28, 2010, the Committee voted in favor of the responses from the centers listed above: 3-Supported; 0-Opposed; 0-Abstained.

The Committee briefly discussed the responses from the following two centers. UNOS staff distributed to the Committee the responses on April 21, 2010.

- Center 08858D (Kidney Program)
- Center 25241D (Kidney Program)

(These centers provided their responses after UNOS staff had distributed the meeting packet on April 14, 2010.) The Committee members commented that they were not able to review these two responses. As there were only three of the eight voting members participating in the meeting, the meeting did not have a quorum. After some discussion, the Committee asked that UNOS staff distribute the responses to all Committee members for their review and vote. UNOS staff commented that if a member objects or has a question about a center's response, the Committee would need to discuss the response further. In other words, a center's response should not be considered satisfactory if even one member raises an objection or question.

In the discussion that resulted in the decision to distribute audit responses electronically for voting, a HRSA representative engaged the Committee and UNOS staff in a dialogue about the consequence to a center if it provided a response that dissatisfied the Committee. One member replied that historically, the Committee had received such a response. In that situation, the Committee requested additional information from the center.

UNOS staff commented that the audit should be performed and the responses evaluated seriously. If a center does not cooperate with the Committee in an audit, then the Committee could refer the center to the Membership and Professional Standards Committee (MPSC). Also, if a particular response causes concerns, the Committee could avail itself of site visit services performed by the UNOS Department of Evaluation and Quality. The findings of the site visit could generate an action by the Membership and Professional Standards Committee.

UNOS staff commented that center #25241D responded that it corrected its candidates' citizenship status in cases where the candidates had been incorrectly recorded as being non-resident aliens. This data modification changed the total number of non-resident alien transplants that this center performed in 2008. UNOS staff also stated that this center had made such corrective changes once before due to the Committee's audit. It appears that the center's data coordinator did not understand the definition of non-resident alien. The Committee was not concerned about the corrections as the need for it was due to a misunderstanding of the non-resident alien definition, a concern that the Committee has already identified and is addressing.

UNOS staff will collect electronically the remaining Committee votes.

## **Review of Non-Resident Alien Transplantation Data (2009)**

The Committee briefly reviewed the non-resident alien transplantation rates in the 2009 calendar year. The Committee's meeting packet included the non-resident alien transplantation data for 12 transplant programs (11 centers) that exceeded the 5% rate in 2009. The data presented for each center included data by citizenship type and for the 2006-2009 calendar years. The data also identified for each center which of its transplant programs exceeded the 5% rate. Based on previous, Committee-approved methodology, UNOS staff presented non-resident alien transplant data for only programs that exceeded the 5% due to two or more transplants. The historical data presented, i.e., for the 2006-2008 calendar years, did not apply this methodology. Upon a query from the UNOS staff, the Committee agreed to continue to apply this methodology in its review of the 2009 data.

UNOS staff provided an overview of the non-resident alien transplant rate for three of the 12 programs. The Committee decided to audit one program because its 2009 non-resident alien transplant rate was 25.0%, even though this program's 2008 rate was 3.7%. The Committee had concerns about auditing a second program that had a 7.7% non-resident alien transplant rate in 2008 and 2009. Here, the Committee commented that the number of transplants in non-resident aliens was small compared to the total number of transplants. The Committee voted to audit a third program that had a 15.4% non-resident alien transplant rate in 2009, even though this program's 2008 rate was 11.1% and due to one transplant.

UNOS staff commented that Policy 6.3 (Audit) that the Committee will audit programs that exceed the 5% rate (see below). The Committee can choose to exclude from the audit process programs that transplant a small number of non-resident aliens, but may want to have this methodology included in the policy language. With the exception of such small programs, it may be most prudent for the Committee to audit any program that exceeds the 5% non-resident alien transplant rate annually, as this interpretation would be best understood by the larger community. Further, the audit process is not punitive. The Committee agreed and decided to audit all 12 programs that exceeded the 5% rate in 2009.

6.3 AUDIT. 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 will distribute audit letters to all 12 transplant programs that exceeded the non-resident alien transplant rate of 5% in 2009.

## **Proposed Modifications to Policy 6.4.4 (Ethical Practices)**

To build consensus on the Committee's proposed modification to Policy 6.4.4, UNOS staff had shared with the following Committees a draft of the Committee's public comment proposal: Ethics and Living Donor. Once these Committees provide feedback, UNOS staff will share this information with the Committee.

## **Proposed Modifications to Policies 6.4.2 (Developmental Protocols in International Organ Exchange) and 6.4.3 (Ad Hoc Organ Exchange)**

To build consensus on the Committee’s proposed modification to Policy 6.4.2 and 6.4.3, UNOS staff had shared with the following Committees a draft of the Committee’s public comment proposal: Ad Hoc Disease Transmission Advisory, Ethics, Operations and Safety, Organ Procurement Organization, Transplant Administrators, and Transplant Coordinators. Once these Committees provide feedback, UNOS staff will share this information with the Committee.

**Status of the Addition of the Waiting List Removal Code “Transplant in Another Country”**

On March 18, 2010, UNOS implemented the addition of the code, “transplant in another country.” If a transplant program selects this code when removing a candidate from the waiting list, it has the option to enter the name of the country where the transplant will take place. If the transplant program does not know the name of the country, then it may select an “unknown” as the answer choice.

As of April 28, 2010, UNOS staff stated that a few transplant programs have made use of this removal code. UNOS staff will continue to monitor and quantify the use of this removal code.

<b>Ad Hoc International Relations Committee</b>	<b>April 28, 2010 Teleconference and Live Meeting</b>	
<b>Name</b>	<b>Position</b>	<b>Attendance</b>
Gloria Garcia Bohrer	Chair	By phone
Gabriel M. Danovitch, MD, LRCP, MRCS	Vice Chair	
Angela Engerson RN	At Large	
Joseph Ferreira	At Large	
Robert L. Kormos MD	At Large	
Barbara J. Nuesse RN,BSN,CCTC,CPTC	At Large	By phone
Marian A. O’Rourke, RN, CCTC	At Large	
Paul Volek, MPH	At Large	By phone
Bernard Kozlovsky, MD, MS	Ex Officio – HRSA	By phone
Elizabeth Ortiz-Rios, MD	Ex Officio – HRSA	By phone
Maria Larkina	SRTR Liaison	By phone
Kerrie Cobb	UNOS Support Staff	By phone
Walter Graham	UNOS Executive Director	By phone
Vipra Ghimire, MPH, CHES	Policy Analyst	By phone
Brian Shepard	Director of OPTN Board and Committee Operations	By phone
Sarah Taranto	UNOS Support Staff	By phone