

OPTN/UNOS Ad Hoc International Relations Committee
Report to the Board of Directors
June 21-22, 2010
Richmond, Virginia
Summary

I. Action Items For Board Consideration

- None

II. Other Significant Items

- *Discussion of Proposed Modifications to Policy 6.1.1 (Non Resident Alien)*

The Committee discussed how to clarify the language in Policy 6.1.1, and modify related policies, if necessary, to maintain the original intent of Policy 6.1.1. (Item 1, page 3)

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

The Committee discussed modifications to Policies 6.4.2 (Developmental Protocols in International Organ Exchange) and 6.4.3 (Ad Hoc Organ Exchange) to enhance the safety of imported deceased donor organs. To develop a consensus on the final policy language, the Committee distributed a draft public comment proposal to interested Committees for review. The Committee will review the commentary in the third quarter of 2010. (Item 2, page 6)

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

The Committee continues to modify Policy 6.4.4. To develop a consensus on the final policy language, the Committee distributed a draft public comment proposal to interested Committees for review. The Committee will review the commentary in the third quarter of 2010. (Item 3, page 10)

- *Response to the Committee's Audit Letters Inquiring about Non-Resident Alien Transplants that Exceeded 5% in the Calendar Years 2007 and 2008*

The Committee reviewed responses to its audit from six transplant programs (five transplant centers). The Committee found the responses satisfactory and did not request additional information from these programs. (Item 4, page 11)

- *Review of Centers that Exceeded the Non-Resident Alien Transplantation Rate of 5% in 2009*

In 2010, the Committee will audit 12 transplant programs (11 centers) that exceeded the 5% non-resident alien transplant rate in 2009. (Item 5, page 13)

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Gloria Garcia Bohrer, Chair
Gabriel M. Danovitch, MD, LRCP, MRCS, Vice-Chair

The Ad Hoc International Relations Committee met by conference call on January 28, 2010 and April 28, 2010. The following is a summary of the Committee's deliberations:

1. Discussion of Proposed Modifications to Policy 6.1.1 (Non Resident Alien)

At its January 28, 2010 meeting, the Committee reaffirmed its interest in modifying Policy 6.1.1. The Committee maintained that it is not necessary to know the reason for the non-resident's temporary residence in the United States. The Committee also considered alternative wording to the policy modification, as written below:

~~“An non-resident alien is an individual granted permission by the 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.”~~

In its previous discussions, the Committee discussed and supported the following policy revision:

~~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.~~

The Committee requested again that UNOS staff develop a proposal to modify Policy 6.1.1, and specifically, to eliminate the “granted permission by the United States” phrase. The Committee will consider which modified policy language it prefers when it evaluates the draft public comment proposal. The Committee reiterated its intent to modify the policy: 1) to not disenfranchise a possible candidate population (i.e., undocumented); and, 2) to promote transplant centers to continue formulating decisions on who to list for transplant based on medical criteria and not non-medical criteria (i.e., citizenship status). The Committee requested that UNOS staff prepare the proposal for distribution in the March, 2010 public comment cycle.

In February, 2010, during the policy proposal development phase, several members of UNOS leadership and the policy analyst for the Committee met to discuss the political consequences of distributing the proposed policy modification for public comment. This group determined that the Executive Committee should discuss the Committee's interest in modifying Policy 6.1.1, and provide relevant guidance.

The Committee prepared an argument for and against the policy change, and posed the following questions to the Executive Committee:

- 1) May the Committee proceed with its activity to modify Policy 6.1.1 as described above, and distribute the resulting proposal for public comment?
- 2) If the Committee may proceed with the distribution of the public comment proposal, what political and evidential guidance from Executive Committee should the document include?

- 3) Should the OPTN delete the non-resident alien definition from policy, and refer its constituents to the definition that resides in UNetSM help documentation?
- 4) Are there other alternatives for the Committee to pursue?

On April 19, 2010, the Executive Committee met but did not review the Committee's arguments for and against the proposed modifications to Policy 6.1.1.

On April 28, 2010, the Committee discussed how best to proceed with its interest in modifying Policy 6.1.1. The Committee commented that advice from UNOS General Counsel would be necessary to avoid any legal consequences 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 current 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 UNetSM and not for the purposes of guiding clinical practice of transplant programs. A transplant program has the choice to select which candidate, regardless of citizenship, to list for transplantation. Neither the OPTN nor its policies interfere with this center-specific decision. 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 UNetSM 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 the nondiscrimination language in 6.2.1. While this interpretation is correct, 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 the subject of 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 alien 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 residents for transplantation, it appears necessary to clarify the non-resident alien construct and its application in policy. Thus, 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 residents. 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 – and determine if immigration status is a barrier to transplantation. Further, given the current national discussions occurring about undocumented individuals, the Committee may want to consider remaining silent on this topic until such immigration decisions are made by the federal government.

The Committee 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 UNetSM; and Policy 6.3 (Audit) states 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 may refocus Policy 6.0 (Transplantation of Non-Resident Aliens) on people who travel to the United States for transplantation, instead of 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. UNOS staff will 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.

2. Proposed Modifications to Policies 6.4.2 (Development Protocols in International Organ Exchange) and 6.4.3 (Ad Hoc Organ Exchange)

At its January 28, 2010 meeting, the Committee reviewed proposed revisions to Policies 6.4.2 and 6.4.3. The revisions followed the guidance provided by representatives of the following OPTN/UNOS Committees in 2009: Disease Transmission Advisory, Operations and Safety, Organ Procurement Organization, Transplant Administrators, and Transplant Coordinators. UNOS staff commented that the proposed revisions focus on the imports of foreign deceased donor organs, as Policy 6.4.1 (Exportation) states clearly that OPOs may only export a deceased donor organ from the United States after having first exhausted the national match-run for that organ. So, in the revised version, Policy 6.4.2 focuses on formal agreements to import deceased donor organs from foreign agencies; and Policy 6.4.3 focuses on ad hoc imports of deceased donor organs.

The Committee supported the revisions, and recommended that UNOS staff proceed with the proposal development. The Committee will review the policy in greater detail when it reviews the draft of the related public comment proposal. The proposed revisions to Policies 6.4.2 and 6.4.3 are below.

6.4.2 Organ Import Arrangement. After prior approval by the OPTN Board of Directors, a member or members may enter into a formal organ import arrangement with a foreign transplant program or programs. This arrangement may only be in place for deceased donor organs. Further, each arrangement may not exceed two years in duration. Importation of organs is defined in Policy 6.4.5 (Importation).

A proposed international organ exchange protocol must be submitted to the OPTN Contractor for review. This protocol must describe the rationale for the arrangement; expected benefits to both foreign and domestic participants; include credentials of the foreign participant; detail the number and type of organs anticipated to be exchanged; include a plan for allocating the organ; and, report results of the exchange arrangement.

A proposed protocol must address laboratory testing and safety of the imported organ; legitimacy of the foreign participant; and, ethical procurement and transplantation practices of the foreign participant or participants. The organ import process must meet the organ procurement and transplantation ethical practices described in Policy 6.4.4 (Ethical Practices). At a minimum, a proposed protocol submitted to the OPTN Contractor must include the following documentation:

- Certification from each foreign participant that it has legal and other professional credentials to engage in organ procurement and transplantation in the participant's country (see Policy 6.4.2.3);
- Certification from the donor organization that it obtained informed consent from the donor or his or her legal representative;
- Certification from the donor organization that the donor has met brain death

standards for domestic organ procurement in compliance with the participating member's state law), or donation after cardiac death (DCD) protocols for domestic organ procurement in compliance with the Bylaws (see Appendix B, Attachment III);

- Donor's ABO, minimum serologies, and medical/social history, as outlined in policy (see Policies 2.2-2.5, 3.5-3.8, 3.11, and 4.0); and,
- Member's compliance with Policy 6.4.4.

The Ad Hoc International Relations Committee will review each proposed protocol, render a decision on the protocol, and request that the Board of Directors act on its recommendation, if appropriate.

6.4.2.1 Notification and Allocation of an Organ Imported Through an Approved Organ Import Agreement. The member must report each deceased donor organ import event within 72 hours of the occurrence to the OPTN Contractor's Organ Center. An imported organ will be allocated first within the local area of the OPO that arranged the importation of the organ, but this organ distribution must be in accordance with the allocation policy for that organ. If no recipient is found within the local area of the OPO that arranged the importation of the organ, then the organ shall be allocated outside the local area in a manner consistent with the allocation policy or policies which apply to that organ.

OPOs are required to execute the Match System (UNetSM) for the allocation of all imported, deceased donor organs. The importing OPO must provide the minimum required information about the foreign donor consistent with Policy 3.5.9 (Minimum Information/ Tissue for Kidney Offer), Policy 3.6.9 (Minimum Information for Liver Offers), Policy 3.7.12 (Minimum Information for Thoracic Organ Offers, and Policy 3.8.5 (Minimum Information for Pancreas Offers) and comply with the ABO verification requirements in accordance with Policy 3.2.4 (Match System Access).

6.4.2.1.1 Legitimacy of the Foreign Participant in an Organ Import Arrangement. Importation of an organ for human transplantation in the United States is appropriate only if the foreign source is an organ transplant center or organ procurement program specifically authorized as a transplant center or organ procurement program by an appropriate agency of its national government. The OPO or transplant center that imports an organ through an Organ Import Arrangement must obtain official documentation from the exporting party that it is a medical center authorized to export organs for transplantation.

6.4.2.2 Review of Approved Organ Import Protocols. The Ad Hoc International Relations Committee will review annually all approved organ import protocols.

6.4.3 An Ad Hoc Organ Import. All offers of organs for human transplantation from foreign sources must be made to the OPTN Contractor's Organ Center. If a member is contacted by a foreign program with an organ offer, that member must notify the OPTN Contractor's Organ Center of that offer within 72 hours of the offer. No more than six imports by any member will be allowed on an ad hoc basis. Additional organ imports must be made as part of an international organ import agreement arrangement (see Policy 6.4.2) that has been approved by the Ad Hoc International Relations Committee and Board of Directors.

Imports of organs (see Policy 6.4.5) from foreign sources on an ad hoc basis must meet the requirements for the importation and allocation of those organs described in Policy 6.4.2.1.1.

Through collected documentation, the participating member must address laboratory testing and safety of the organ or organs, and ethical procurement and transplantation practices of each foreign participant involved. An organ imported into the United States must meet this country's organ procurement and transplantation ethical practices (see Policy 6.4.4). At a minimum, for each organ import event, the member must collect the following documentation:

- Certification from each foreign participant that it has legal (i.e., government authorized) and other professional credentials to engage in organ procurement and transplantation in the participant's- country (see Policy 6.4.2.3);
- Certification from the donor organization that it obtained informed consent from the donor or his or her legal representative;
- Certification from the donor organization that the donor has met brain death standards for domestic organ procurement in compliance with the participating member's state law, or donation after cardiac death (DCD) protocols for domestic organ procurement in compliance with the Bylaws (see Appendix B, Attachment III);
- Donor's ABO, minimum serologies, and medical/social history, as outlined in policy (see Policies 2.2-2.5, 3.5-3.8, 3.11, and 4.0); and,
- Member's compliance with Policy 6.4.4 (Ethical Practices).

The member is strongly urged to confirm the results of any serologic tests performed outside of the United States at the member's affiliated laboratory in the United States. It is the responsibility of the member to translate into the English language, if necessary, any relevant document collected from a foreign participant.

6.4.3.1 Ad Hoc Organ Import Review. Each ad hoc organ import occurrence will be reviewed annually by the Ad Hoc International Relations Committee.

The following is *existing language in Policies 6.4.2 and 6.4.3* and this language is struck to indicate that it will be modified and submitted for public comment:

~~**6.4.2 Developmental Protocols in International Organ Exchange.** After prior approval by the OPTN, members may enter into formal organ exchange arrangements, each not to exceed two years in duration, with a foreign transplant program or programs. Negotiations with foreign transplant programs or foreign agencies which include importing organs must be approved by the Ad Hoc International Relations Committee. Importation of organs is defined in Policy 6.4.5 (Importation). Proposed protocols must be submitted to the OPTN describing the basis for such arrangements, expected benefits to both foreign and domestic participants, credentials of the foreign source, number and type of organs anticipated to be involved, and plans for allocation procedures and reporting of results. Proposed protocols must include a requirement for the donor organization to submit documentation certifying the informed consent of the donor or his or her legal representative. Proposed protocols~~

must also include a requirement for the donor organization to submit documentation certifying that the donor has met the met brain death or donation after cardiac death (DCD) protocols that are in compliance with recognized U.S. standards for domestic organ procurement. Proposed protocols must include a requirement for the donor organization to submit documentation of the donor's ABO. Proposed protocols will be reviewed by the Ad Hoc International Relations Committee, which will then make recommendations to the Board of Directors.

~~6.4.2.1~~ All foreign organ exchanges must be reported within 72 hours to the Organ Center. All exchanges must satisfy policy that no organs can be exported from the United States without first a determination having been made by the Organ Center that there is no suitable recipient for that organ on the Waiting List. All imported organs will be allocated first within the local area of the OPO that arranged the importation of the organ and in accordance with the allocation policy for that organ. If no recipient is found within the local area of the OPO that arranged the importation of the organ, then the organ shall be allocated outside the local area in a manner consistent with the policies which apply to that organ.

OPO's are required to execute the Match System (UNetsm) for the allocation of all organs. The importing OPO must provide the minimum required information about the foreign donor consistent with Policy 3.5.9 (Minimum Information/ Tissue for Kidney Offer), Policy 3.6.9 (Minimum Information for Liver Offers), Policy 3.7.12 (Minimum Information for Thoracic Organ Offers, and Policy 3.8.5 (Minimum Information for Pancreas Offers) and comply with the ABO verification requirements in accordance with Policy 3.2.3 (Match System Access).

~~6.4.2.2~~ All approved international organ exchange protocols will be reviewed at least annually by the Ad Hoc International Relations Committee. Any additional policies regarding international exchange agreements will be developed by the Committee based on experience acquired pursuant to approved developmental protocols. It is a goal of the OPTN that international exchange of organs between OPTN members and foreign programs will foster the development of international organ sharing. It is hoped that such exchanges will occur through the regular national OPTN system, after feasibility has been established.

~~6.4.2.3~~ Importation of an organ for human transplantation in the United States is appropriate only if the foreign source is an OPTN recognized source, i.e., organ transplant center or organ procurement program specifically authorized as a transplant center or organ procurement program by an appropriate agency of its national government. The OPO or transplant center responsible for importation of an organ must obtain official documentation from the exporting party that it is a medical center authorized to export organs for transplantation.

~~6.4.3~~ **Ad Hoc Organ Exchange.** Except as provided for in approved international exchange protocols, all offers of organs for human transplantation from foreign sources must be made to the Organ Center. If a member is contacted by a foreign source with an organ offer, that member must notify the Organ Center of that offer. No more than six exchanges by any member with any foreign program(s) will be allowed on an ad hoc basis. Additional exchanges must be made as part of an international organ exchange protocol approved by the Ad Hoc International Relations Committee and Board of Directors.

~~Imports of organs from foreign sources on an ad hoc basis must meet the requirements for importing organs and allocation of those organs under organ exchange protocols found in Policy 6.4.2.1. Additionally, organs imported by OPOs must include documentation certifying that the donor has met brain death or donation after cardiac death (DCD) protocols that are in compliance with recognized standards for domestic organ procurement. Organs imported by OPOs must include documentation from the donor organization certifying the informed consent of the donor or his or her legal representative. Organs imported by OPOs must include documentation from the donor organization verifying the donor's ABO.~~

~~**6.4.3.1 Ad Hoc Organ Exchange Review.** Ad hoc organ exchange will be reviewed annually by the Ad Hoc International Relations Committee.~~

In order to build consensus on these proposed modifications to Policy 6.4.2 and 6.4.3, the Committee shared a draft of the public comment proposal with the following Committees: Ad Hoc Disease Transmission Advisory, Ethics, Operations and Safety, Organ Procurement Organization, Transplant Administrators, and Transplant Coordinators. The Committee will review the feedback provided.

3. Proposed Modifications to Policy 6.4.4 (Ethical Practices)

On January 28, 2010, the Committee reviewed the following current language in Policy 6.4.4 and proposed revisions to it.

- Current Policy Language:

6.4.4 Ethical Practices. No member will engage in practices which might discredit the transplant community. Organs accepted for importation must be from deceased donors and must have been voluntarily donated. Organs imported from living donors or organs for which compensation has been made or promised are not acceptable for exchange or acceptance by members.

- Proposed Modification:

6.4.4 Ethical Practices. ~~No A member will~~ must not engage in ~~a~~ practices which might that ~~discredits~~ discredits the transplant community. ~~A Member may only accept an imported organ that the respective donor or his or her designee donated voluntarily. Members cannot accept an imported organ that has valuable consideration.~~ Organs accepted for importation must be from deceased donors and must have been voluntarily donated. Organs imported from living donors or organs for which compensation has been made or promised are not acceptable for exchange or acceptance by members.

Though the phrase “valuable consideration” may not fall in the category of “plain language;” however, this term addresses the scope of an organ market far better than the term that is in the policy now – “compensation.” Therefore, the Committee favored the use of the term “valuable consideration.” The Committee proposed the following alternative wordings:

- Alternative 1 (Insert “Knowingly”):

A Member must not engage in a practice that discredits the transplant community. A Member may only accept an imported organ that the respective donor or his or her designee donated voluntarily. Members cannot accept *knowingly* an imported organ that has valuable consideration.

- Alternative 2 (Insert “Concern” Concept):

A Member must not engage in a practice that discredits the transplant community. A Member may only accept an imported organ that the respective donor or his or her designee donated voluntarily. Members cannot accept an imported organ if there is concern that the organ might have valuable consideration.

The current policy focuses on the OPTN member. Should the policy address transplant recipients? The Committee responded that the focus need not be on recipients for this policy. Should the policy apply to both deceased and living donor organs? It was asked when a member would import a living donor organ. UNOS staff commented that in kidney-paired donation scenarios where one individual may reside outside of the United States, it is possible that this individual may wish to have organ procurement occur in his or her home country. In this circumstance, though very rare, the living donor organ would be imported. The Committee then commented that members must not accept a deceased or living donor organ for valuable consideration.

The Committee then re-reviewed its policy language alternatives (see above). The Committee commented that the use of “knowingly” would be a valuable insertion, and recommended development of the public comment proposal to modify Policy 6.4.4 as described in Alternative 1 above.

To build consensus on the Committee’s proposed modification to Policy 6.4.4, the Committee shared with the following Committees a draft of the public comment proposal: Ethics and Living Donor. The Committee will review the feedback provided.

4. Response to the Committee’s Audit Letters Inquiring about Non-Resident Alien Transplants that Exceeded 5% in the Calendar Years 2007 and 2008

On January 28, 2010, UNOS staff reported that it is awaiting responses to the Committee’s audit of programs that exceeded the 5% rate in the 2007 and 2008 calendar years. UNOS staff distributed the letters in January, and anticipates receiving the responses by the end of February. The Committee will discuss the responses at its next Committee meeting.

On April 28, 2010, 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 non-resident alien transplant rate for the 2007 calendar year. 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. The Committee, however, maintained the following methodologies: 1) audit only programs that exceeded the 5% rate for two consecutive years, including the year under review; and 2) audit only programs that exceeded 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 the 2006 and 2007 calendar years. 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 the 2007 and 2008 calendar years. 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 the 2008 calendar year. UNOS staff advised this center's intestine program to submit a response to the Committee's audit for only the 2008 calendar year. UNOS staff had included in the Committee packet for the April 28, 2010 meeting this intestine program's 2007 response. (When the Committee had reviewed this intestine program's response to the audit for the 2007 calendar year, it had voted in favor of the response.)

On April 28, 2010, the Committee voted to accept the responses from the three centers listed above, without further review: 3-Supported; 0-Opposed; 0-Abstained.

The Committee briefly discussed the responses from the following two centers. (UNOS staff had distributed to the Committee the responses from these centers on April 21, 2010, as these centers provided their responses after the distribution of the Committee meeting packet on April 14, 2010.)

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

The Committee members commented that they had not had an opportunity 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 to or question about it.

In the discussion that resulted in the decision to distribute audit responses electronically for voting, a representative from the Health Resources and Services Administration (HRSA) engaged the Committee and UNOS staff in a dialogue about the consequence to a center that provided a response found unsatisfactory by the Committee. One member replied that historically, the Committee had received such a response. In that situation, the Committee had 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 (DEQ). The findings of the site visit could generate an action by the MPSC.

Center #25241D responded that it corrected its candidates' citizenship statuses 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 votes on responses submitted by the five centers from members who did not participate in the April 28, 2010 meeting.

Following the April meeting, UNOS staff emailed all Committee members to vote on the responses from the five transplant centers. Five Committee members voted electronically, and the votes and one comment are presented below. None of the five members who voted requested additional information from the centers. In May, 2010, UNOS staff will contact the transplant programs and notify them that the Committee was satisfied with the responses.

- Center 30659D (Liver Program)
5-Satisfied with response; 0-Dissatisfied with response; 0-Abstained
- Center 15222D (Intestine and Liver Programs)
5-Satisfied with response; 0-Dissatisfied with response; 0-Abstained
- Center 15867D (Kidney Program)
5-Satisfied with response; 0-Dissatisfied with response; 0-Abstained
- Center 08858D (Kidney Program)
5-Satisfied with response; 0-Dissatisfied with response; 0-Abstained

One Committee member made the following comment: "Still seems like a lot, but as [UNOS Staff] put it so succinctly, so what? They could do 50%, tell us that it's representative of their community, and we'd have nothing to say. As long as they're allocating legally, MPSC doesn't care. Maybe we should discontinue reviewing these."

- Center 25241D (Kidney Program)
5-Satisfied with response; 0-Dissatisfied with response; 0-Abstained

5. Review of Centers that Exceeded the Non-Resident Alien Transplantation Rate of 5% in 2009

The Committee briefly reviewed the non-resident alien transplantation rates in the 2009 calendar year. The Committee received the non-resident alien transplantation data for 12 transplant programs (11 transplant 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.) 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 alien recipients 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) states 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.

6. Discussion of the Living Donor Committee's Proposal to Add a Valuable Consideration Disclosure to the Bylaws

On January 28, 2010, the Committee discussed the following proposal sponsored by the OPTN/UNOS Living Donor Committee (Living Donor Committee):

- Affected Bylaws: Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation and Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Living Donor Liver Transplantation

This proposal would require transplant centers to document that potential living organ donors were informed that participating in the sale or purchase of human organs is criminal behavior subject to federal prosecution.

The Committee addressed three concepts when it discussed this proposal: 1) there is already a federal prohibition on the sale and purchase of human organs, and therefore, this proposal appears to institute only a benign regulation; 2) benign regulations that task the community are not necessary; and, 3) there is no mention that the prohibition applies to the potential living donor recipient.

The Committee also engaged in a philosophical discussion about how to comment on proposals in general. When a Committee puts forth a proposal, shouldn't the assumption be that it worked hard on developing the concepts therein, i.e., gathering evidence and recommending a policy or bylaw

through the use of expert advice? Is it really the other Committees' responsibility to critique the proposal, risking the perception of being obstructive? The public comment period is for Committees and the public to evaluate proposals. This period is a time for critique, and such evaluations are not obstructive. These assessments are productive and sought by the Committees that propose policy or bylaw modifications. This evaluation could result in the support or opposition of proposals, as well as suggestions for policy modifications.

The majority of the Committee voted to support the proposal: 3-supported; 1-opposed; and, 0-abstained. However, the Committee requested that the following question and comment be forwarded to the Living Donor Committee:

- Shouldn't recipients also be advised that purchase of organs is criminal?
- There is already a federal law prohibiting the sale and purchase of human organs. This proposal addresses only one-half of the transaction.

7. Status of Proposed Change to the Committee's Charge

On January 28, 2010, the Committee learned that the Board of Directors will review the following modification to the Committee's charge at its June, 2010 meeting.

- The Ad Hoc International Relations Committee considers issues related to organs and patients that enter the U.S., or leave the U.S. for transplant. It reviews emerging issues related to U.S. candidates who seek transplants in other countries, and it considers the medical, scientific, and ethical aspects of transplanting non-resident aliens. The committee considers the broad implications of such issues and may review specific individual issues or situations.

The Committee stated its strong support of this change. The Committee commented that it is unclear on how to enable members to report or manage recipients who received transplant outside of the United States. This issue will be considered for inclusion in the Committee's annual goals.

The OPTN President and the UNOS Executive Director will review and evaluate the Committee's proposed change to the charge. The Board of Directors will not need to review this modification.

8. Programming to Add "Transplant in another Country" As a Removal Code in the Waiting List Removal Page

On January 28, 2010, the Chair updated the Committee on the following implementation effort:

- Addition of "Transplant in Another" Country and "Name of Country" to the Waitlist Removal page

The addition of these data elements will occur on or before April 19, 2010.

The Chair requested volunteers to test the final product. Members interested in evaluating the functionality of the implemented data elements would do so using test cases, not actual cases. UNOS staff would coordinate the testing help documentation and not case. One member volunteered to be an external tester, and UNOS staff will ask another transplant administrator or coordinator on the Committee to be the second tester.

On April 28, 2010, the Chair stated that 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, 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.

9. General Information

On January 28, 2010, the Committee thanked UNOS staff for including recent newspaper articles related to transplantation and non-resident aliens. The Committee may discuss the slide set on import and export data at its next meeting.

Ad Hoc International Relations Committee	January 28, 2010 Teleconference and Live Meeting	
Name	Position	Attendance
Gloria Garcia Bohrer	Chair	By phone
Gabriel M. Danovitch, MD, LRCP, MRCS	Vice Chair	By phone
Angela Engerson RN	At Large	By phone
Joseph Ferreira	At Large	
Robert L. Kormos MD	At Large	
Barbara J. Nuesse RN,BSN,CCTC,CPTC	At Large	
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
Diane Steffick	SRTR Liaison	By phone
Kerrie Cobb	UNOS Support Staff	By phone
Vipra Ghimire, MPH, CHES	Policy Analyst	By phone
Sarah Taranto	UNOS Support Staff	By phone

Ad Hoc International Relations Committee	April 28, 2010 Teleconference and Live Meeting	
Name	Position	Attendance
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