

At-a-Glance

- **Proposed Revisions to and Reorganization of Policy 6.0 (Transplantation of Non-Resident Aliens), Which Include Changes to the Non-Resident Alien Transplant Audit Trigger Policy and Related Definitions**
- **Affected Policies:** 6.0 and 3.2.1.4 (Prohibition of Organ Offers to Non-Members)
- **Sponsoring Committees:** Ad Hoc International Relations; Ethics

This proposal clarifies the data collected about the citizenship and residency of donors and recipients. The proposal also amends the audit trigger policy, allowing the Ad Hoc International Relations Committee to review the circumstances of any transplant of non-US residents/non-US citizens and make a public report. The proposal also contains technical amendments and removal of requirements that are not enforceable.

- **Affected Groups**
 - Directors of Organ Procurement
 - Laboratory Directors
 - Laboratory Supervisors
 - OPO Executive Directors
 - OPO Medical Directors
 - OPO Coordinators
 - Transplant Administrators
 - Transplant Physicians
 - Transplant Surgeons
 - Public Relations Staff
 - Public Education Staff
 - Transplant Program Directors
 - Organ Candidates
 - General Public
- **Number of Potential Candidates Affected**

The proposed modification will apply to non-US/residents-non/US-citizens.
- **Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:**

The proposed policy modification addresses the “best use” program and strategic plan goal of the Health and Human Services and the OPTN, respectively, and the following constructs in the OPTN Final Rule:

§121.8 Allocation of organs. (a) Policy development. [...] (6) Shall be reviewed periodically and revised as appropriate; [...]
- **Specific Requests for Comment**

Please comment specifically on Policies 6.1, 6.2, and 6.3, as well as on the entire policy proposed for public comment.

Proposed Revisions to and Reorganization of Policy 6.0 (Transplantation of Non-Resident Aliens), Which Include Changes to the Non-Resident Alien Transplant Audit Trigger Policy and Related Definitions

Policies Affected: 6.0 and 3.2.1.4 (Prohibition of Organ Offers to Non-Members)

Sponsoring Committees: Ad Hoc International Relations; Ethics

Summary and Goals of the Proposal:

This proposal is designed to clarify the data collected about the citizenship and residency of transplant recipients in order to evaluate the extent to which patients are travelling to the US for purposes of transplantation. The proposal also redesigns the current policy for the audit of transplant programs that perform deceased donor transplants of patients who are non-US citizens and who do not reside in the US. To promote an additional goal of enhanced transparency, the proposed policy will allow the Ad Hoc International Relations Committee to review the circumstances of any deceased donor transplant of non-US residents/non-US citizens and to make available to the public a report regarding the extent to which international patients are travelling to the US for deceased donor transplantation. The goal of the data collection, audit and reporting under this policy proposal is to evaluate and to make publically transparent the extent of travel to the US for transplant and whether such practices are contributing to transplant tourism by undermining the ability of the US to provide transplantation services for its own population. The proposal also contains technical amendments and removal of requirements that are not enforceable.

Background and Significance of the Proposal:

The Ad Hoc International Relations Committee and the Ethics Committee (Committees) recognize the dramatic changes that have taken place in the relative availability of transplant services to patients outside of the US since Policy 6.0 was first adopted. Given these changes, the Committees concluded that Policy 6.0 requires revisions to reflect the need for more complete data collection regarding the international patients utilizing the US transplantation network. The Committees were also concerned that both the letter and spirit of Policy 6.0 with respect to “community participation” as a measure of transparency and public accountability were not being honored. The current realities of travel for transplantation and transplant tourism require appropriate oversight and transparency of the system in order to maintain public trust. Accordingly, the Committees propose changes to Policy 6.0 that focus on evaluating the extent to which patients are travelling to the US for deceased donor transplantation and increasing public transparency regarding these circumstances.

In identifying the problem the Committees seek to solve by this proposal, the Committees were influenced by the *Declaration of Istanbul on Organ Trafficking and Transplant Tourism*,^[1] specifically the concepts of travel for transplantation and transplant tourism, which are defined as follows:

“Travel for transplantation is the movement of organs, donors, recipients or transplant professionals across jurisdictional borders for transplantation purposes. Travel for

^[1] In March, 2009, the Board of Directors adopted the definitions in the *Declaration of Istanbul* for “organ trafficking,” “transplant commercialism,” “transplant tourism,” and “travel for transplantation.”
http://optn.transplant.hrsa.gov/SharedContentDocuments/Executive_Summary0309.pdf

transplantation becomes **transplant tourism** if it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals and transplant centers) devoted to providing transplants to patients from outside a country undermine the country's ability to provide transplant services for its own population."^[2]

As to the first goal of these proposed modifications, the Committees believe the OPTN should collect information to determine the extent to which patients are travelling to the US for purposes of deceased donor transplantation and ultimately whether these practices undermine the ability of the US to provide transplant services for its own population. The Committees concluded that the present definitions in Policy 6.0 and the related data collection fields on OPTN forms do not collect the information necessary to make this determination. Accordingly, the proposal revises the definitions in Policy 6.1 into two categories: (1) Non-US Citizens, non-residents, and (2) Non-US Citizens, US residents. The goal in creating these categories is to focus on the category of patients who do not reside in the US and are travelling to the US for purposes of transplantation.

The proposal changes the current definitions by defining residency simply as whether the patient considers the US as the primary place of residence whereas currently the definition in 6.1 is based on legal immigration status. The Committees feel that this change is important given that the purpose in collecting such information is to evaluate the category of non-US citizen patients who travel to the US for transplantation, and to provide transparency regarding the listing and transplantation of these patients. Given that neither the OPTN nor its members are likely to have immigration expertise, the Committees also felt that collecting data on legal immigration status should not be part of the wait listing process.

The proposed definition of residency is also consistent with the Committees' conclusion that those individuals who reside in the US, regardless of immigration status, may become deceased donors whereas those patients who do not reside in the US may not. As shown in Figure 4 (Supporting Evidence Section), it is clear that under the current category of "non-resident aliens" – many of whom are very likely undocumented residents – provide deceased donor organs for allocation by the OPTN. The Committees assert that this contribution differentiates the population of non-citizens who reside in the US from those non-citizens who travel to the US for transplant purposes, particularly as it relates to considerations of transplant tourism. Accordingly, the proposal is to categorize based on citizenship and residency with a focus on the patients who are non-citizens *and* who do not reside in the US.

As with the current category for "non-resident aliens," the candidate will declare the citizenship or residency categories during the wait listing process. The Committees recognize that self-reporting this type of data has limitations but given that other demographic information is similarly self-reported, the Committees felt this is appropriate.

It is important to note that the proposal does not seek to limit or exclude the ability for non-US citizens/non-residents from being listed for transplantation. Without a clear understanding of the extent to which there are patients travelling to the US or potentially contributing to transplant tourism by undermining the ability of the US ability to provide transplant services to its own population, the Committees did not feel it would be appropriate to even consider such measures.

^[2] The Declaration of Istanbul. "Principles." Accessed July 26, 2011.
http://www.declarationofistanbul.org/index.php?option=com_content&view=article&id=81&Itemid=85

The Committees also recognizes the guidance provided by the Health Resources and Services Administration (HRSA):

“The National Organ Transplant Act (NOTA) requires that OPTN match organs and individuals in accordance with "established medical criteria" and establish "medical criteria for allocating organs." 42 USC 274(b)(2). The plain language of the statute requires that the OPTN base organ allocation policies on medical criteria and does not provide any authority for basing such policy upon United States citizenship or residency status.

The OPTN final rule also does not provide any authority for basing such policy upon United States citizenship or residency status. The regulations specify the use of "objective and measureable medical criteria" and provide no basis for the use of citizenship or residency status in the allocation of organs. 42 CFR 121.8(b).”

The proposed policy changes make no attempt to use citizenship or residency status in the allocation of organs.

Currently, the OPTN collects the year of entry to the United States for reported non-resident alien transplant candidates and living donors, and the home country for reported non-resident alien deceased donors. The OPTN will collect these fields along with the country of permanent residence for all non-resident candidates and living donors, pending programming. In June 2011, the Board of Directors approved a proposal from the Committees to improve data collection regarding the citizenship and residency status of organ donors and recipients. It is important that the language of Policy 6 be revised as proposed to provide the corresponding definitions, and align the policy language with these data elements:

- US Citizen
- Non-US Citizen/US Resident
- Non-US Citizen/ Non-US Resident, Traveled to US for Reason Other than Transplant
- Non-US Citizen/Non-US Resident, Traveled to US for Transplant;

Current OPTN forms require that the date of entry¹ to the US be collected to calculate the length of time from entry to the US until the patient is added to the waiting list. Once this data is gathered, the Committees will be in a better position to evaluate the extent to which the US is a destination for “travel for transplantation,” and to provide greater public accountability and transparency regarding these practices.

The Committees also concluded that the audit provisions of current Policy 6.3 required significant revision. The Committees felt that the audit provision was widely misunderstood as a 5% cap on a transplant center’s ability to list and transplant non-US citizens. At the same time, the Committees concluded that the current audit provision was ineffectual as it lacks clarity on the purpose of the audit and it lacks any criteria regarding transplantation of non-US citizens against which to evaluate the activities of a transplant program. With the defined goal of collecting information to evaluate the circumstances of patients travelling to the US for transplantation, the Committees concluded that providing a percentage above which audit may be triggered was arbitrary and that transparency required that the ability to audit *any time* a patient who is a non US Citizen/Non-resident is listed and

¹ Transplant candidate registration form and the living donor registration form

transplanted. The purpose of the audit is to discern the circumstances of non US citizens/Non-residents obtaining deceased donor transplants in the US (for example, did the patient travel to the US for transplantation that was available or unavailable in the patient's country of residence?), and provide increased transparency regarding these practices.

As the Ad Hoc International Relations Committee framed the problems about Policy 6 and the potential resolutions, it recognized the sensitive nature of Policy 6, and sought advance commentary on Policy 6 from several OPTN/UNOS committees: Minority Affairs Committee (MAC), Patient Affairs Committee (PAC), Transplant Administrators Committee (TAC), Organ Procurement Organization Committee (OPO), Living Donor Committee (LD), and the Operations and Safety Committee (OPS). In April 2011, in order to ensure that changes to Policy 6 appropriately incorporated ethical considerations, the Committee sought a natural partnership with the Ethics Committee. Thus, the proposed policy modifications consider commentary received from all the aforementioned committees, and is jointly sponsored by Committees.

Proposed modifications to Policy 6 are:

1. Change in the title to state the concepts addressed by policy;
2. Revisions to the citizenship definitions, as described above;
3. Deletion of the following policies that cannot be measured or are no longer current:
 - Policies 6.2.2 (Transplant Centers), 6.2.5 (Community Participation), and 6.2.6 (Training Programs) cannot be monitored by the OPTN contractor as written. To re-write these policies so that that the OPTN contractor can monitor them would likely result in language that mandates transplant center behavior that is not related to organ allocation.
 - Policy 6.2.3 (Fees) need not be its own policy as its content aligns well with Policy 6.2.1 (Nondiscrimination/Organ Allocation).
4. Allow the Committee to audit any transplant program that adds to the wait list or transplants candidates who are in the "non-US citizen/non-US resident" category;
 - This audit of listings and transplants will enable the Committee to distinguish between non-US citizens/non-US residents who traveled to the US for transplant, and why, from those who are residents of the US.
5. Delete Policy 6.5 (Violation). This subsection is redundant because all policy violations are subject to review by the OPTN/UNOS Membership and Professional Standards Committee (MPSC);
6. Refocus the current organ exchange section to only organ imports;
 - Policy on deceased donor organ imports is necessary to assure that such organs are clinically safe for transplant; accompany documentation such as consent and type of death; and, are reported to the OPTN contractor.
 - Policy 6.4 (Exportation and Importation of Organs-Developmental Status) does not need to outline the recovery processes related to organ export, as these organs are recovered in the US and policies already address organ recovery requirements.

- Retain the ability to export organs as stated currently but move the language to Policy 3.2.1.4 (Prohibition for Organ Offers to Non-Members), because exportation is an exception to the prohibition of sharing organs with non-members;
7. Retain the ability to import organs ad hoc and through a formal agreement;
 8. Delete the requirement for a program to establish a formal agreement with a foreign agency if it imports more than six ad hoc organs from that foreign agency, because: a) six is an arbitrary number; and, b) the small number (85 transplants with imported deceased donor organs during the 2003 through 2009 time period – see Figure 1) of deceased donor organ imports that occur in a given year do not warrant a policy;

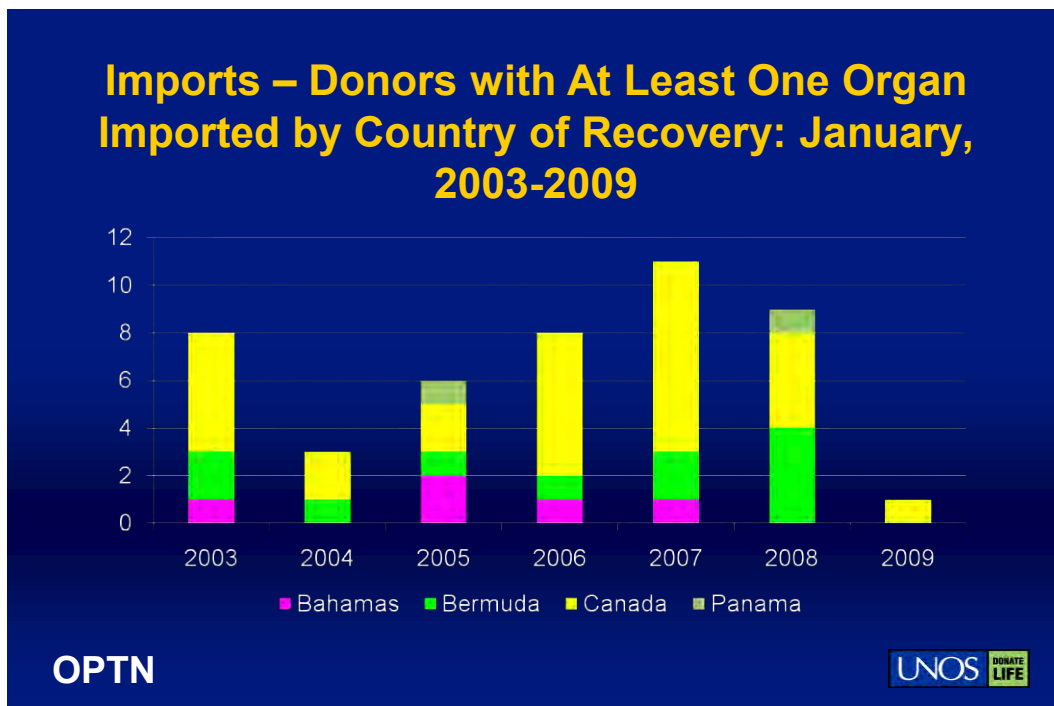


Figure 1: Imports – Donors with at Least One Organ Imported by Country of Recovery: January, 2003-2009 [OPTN Data as of September 8, 2010]²

From 2003 through 2009, there were 85 deceased donor organ transplants performed with organs imported from outside of the US. The number of transplants in any given year ranged from 2 in 2009 and 2004 to 22 in 2007. The number of centers performing these same transplants ranged from 2 to 14 during this period. The majority of these organs were recovered by OPOs with formal agreements to import organs.

9. Delete the policy on ethical practices (6.4.4), because defining the characteristics that constitute ethical practices are subjective and may not be applied consistently within and between professional eras; and,

² New England Organ Bank has a formal agreement to serve as the OPO for recovering deceased donor organs from Bermuda, and the Life Alliance Organ Recovery Agency has a formal agreement to serve as the OPO for recovering deceased donor organs from the Bahamas.

10. Delete language about the import of an organ for valuable consideration, because to do so is a criminal offense that is under the purview of another federal agency.

On August 9, 2011, the Ad Hoc International Relations Committee voted in favor of the proposed policy language: 15-supported; 0-opposed; and, 0-abstained. In August, 2011, the Ethics Committee's leadership approved the policy and approved the submission of the revisions for public comment.

Supporting Evidence:

The number of reported non-resident aliens added to the waiting list for transplant has been around 400 a year in the 2001 through 2010 time period (see Figure 2). This number is much smaller than the number of resident aliens added to the waiting list during the same period. Due to confusion about the current categories, data do not exist currently to differentiate between the numbers of non-resident aliens who are in fact undocumented residents of the US versus international patients who traveled to the US for transplant.

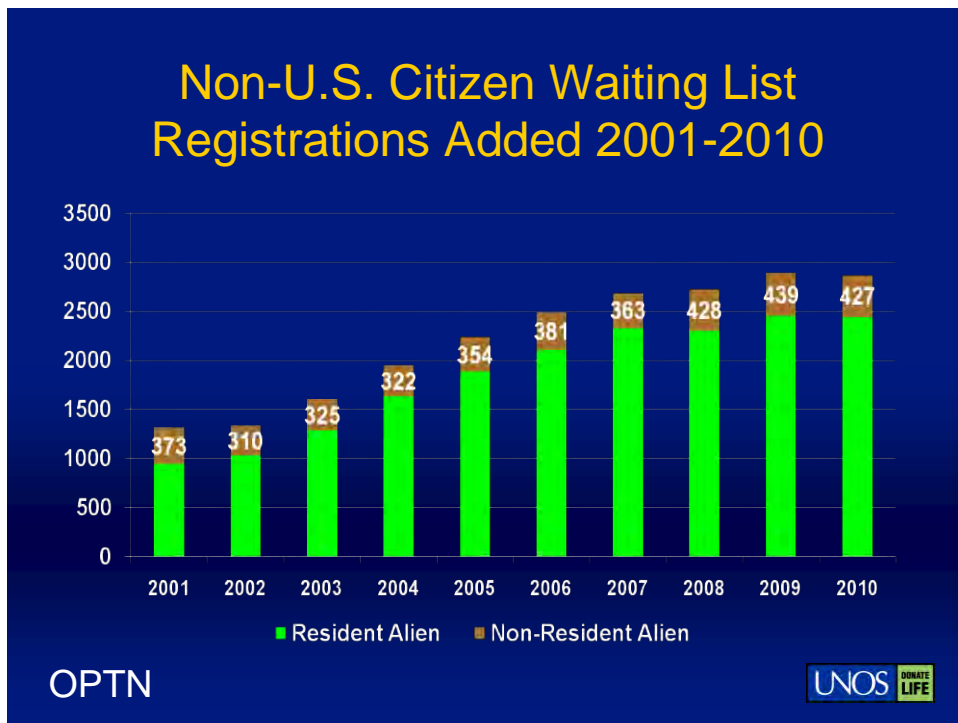


Figure 2: Non-US Citizen Waiting List Registrations Added (2001 to 2010) [OPTN data as of June 15, 2011]

The total number of non-resident aliens who received deceased donor organ transplants remained under 200 per year from 2001 through 2010 (see Figure 3). This number is much smaller than the number of deceased donor transplants for resident aliens during the same period (about 400-800 a year).

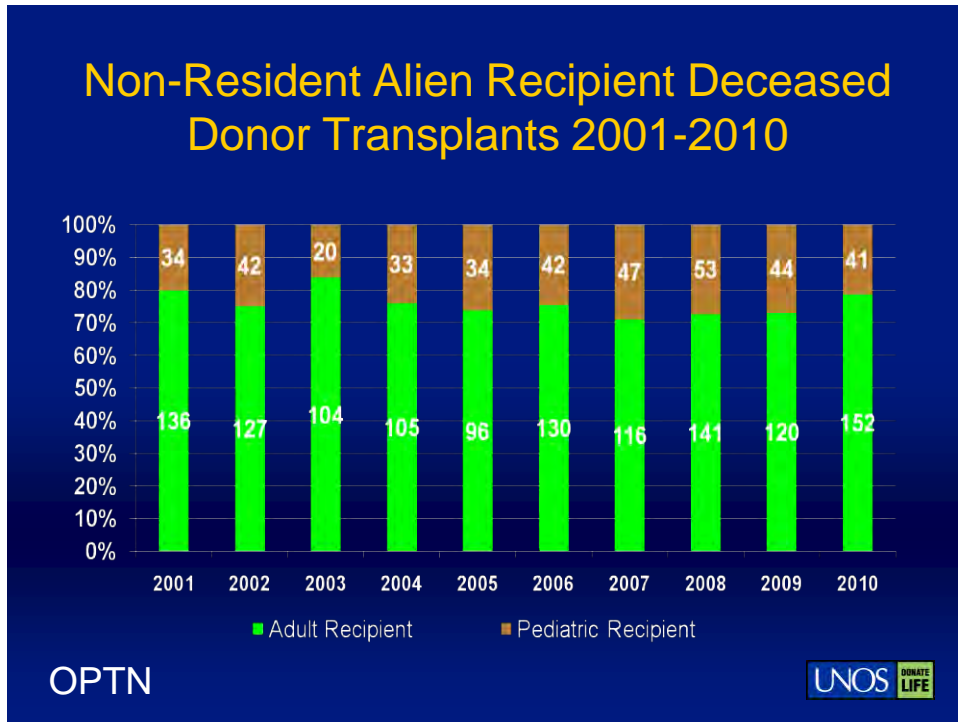


Figure 3: Non-Resident Alien Recipient Deceased Donor Transplants (2001 to 2010) [OPTN data as of June 15, 2011]

Figure 4 shows that deceased non-resident aliens also donate organs for transplantation in the US. The number of transplants from these donors in 2010 was 96, compared to 193 deceased donor transplants performed among non-resident alien recipients. It is possible that some of these deceased donors were in fact visitors to the US

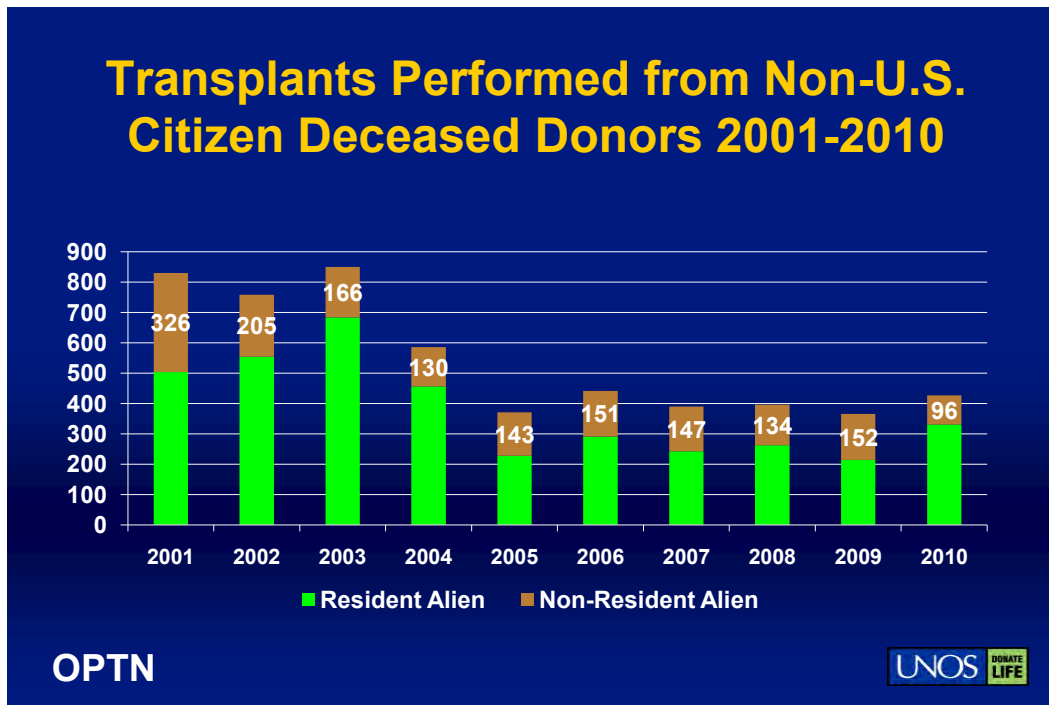


Figure 4: Transplants Performed from Non-US Citizen Deceased Donors (2001 to 2010) [OPTN data as of April 10, 2011]

Figure 5 below shows how long non-resident aliens have been in the United States before being added to the waiting list. Nearly half of these candidates are new arrivals (one year or less) to the US, with the remainder having entered the US at least a couple of year prior to listing. This supports both propositions that 1) some non-resident aliens may be coming to the US for transplant and 2) some non-resident aliens are *de facto* residents who came to the United States for reasons other than transplant.

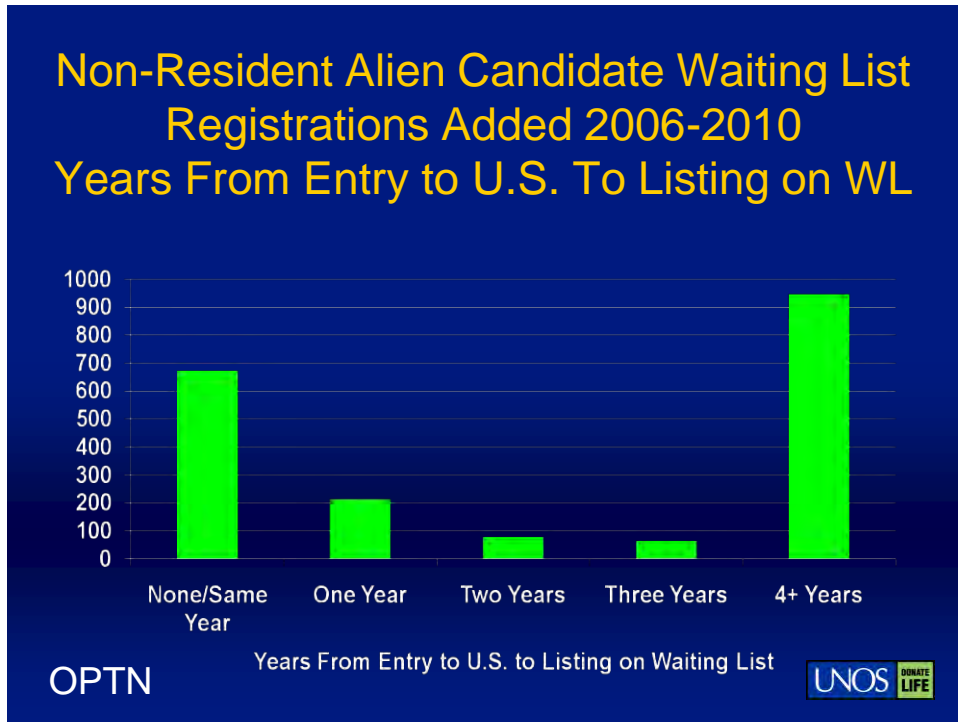


Figure 5: Years from Entry to US to listing on Waiting List Among Non-Resident Alien Candidates [OPTN data as of June 15, 2011]

Expected Impact on Living Donors or Living Donation:

Not applicable

Expected Impact on Specific Patient Populations:

The proposed modification will apply to non-US/residents-non/US-citizens, but will not affect their access to the waiting list or allocation of deceased donor organs.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The proposed policy modification addresses the “best use” program and strategic plan goal of the Health and Human Services and the OPTN, respectively. It is appreciated that there may be compassionate grounds for providing access to the deceased donor list for non-residents. It is understood, however, that visitors to the US whose purpose is to receive deceased donor organ transplants may undermine this country’s ability to provide deceased donor transplants to its own residents. This OPTN Final Rule also requires the periodic review and revision of OPTN policies, including Policy 6.0, which has not undergone revisions in an extended period of time:

§121.8 Allocation of organs.

(a) Policy development. [...]

(6) Shall be reviewed periodically and revised as appropriate; [...]

Ad Hoc International Relations Committee’s Plan for Evaluating the Proposal:

The Ad Hoc International Relations Committee will perform periodic audits of listings and transplants of non-US residents/non-US citizens who receive deceased donor transplants. The OPTN contractor will generate a report for the Committee that lists the centers that add non-US residents/non-US citizens to their waiting list or transplant non-US residents/non-US citizens. The Ad Hoc International Relations Committee will examine cases and follow up with transplant centers for explanation or justification. Transplant centers that do not provide an explanation or fail to respond to inquiries from the Ad Hoc International Relations Committee may be referred to the MPSC.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

This proposal will not require programming in UNetSM.

Communication Plan:

Communication Activity			
Type of Communication	Audience	Deliver Method	Timeframe
Policy Notice	<ul style="list-style-type: none">• Directors of Organ Procurement• Laboratory Directors• Laboratory Supervisors• OPO Executive Directors• OPO Medical Directors• OPO Coordinators• Transplant Administrators• Transplant Physicians• Transplant Surgeons• Public Relations Staff• Public Education Staff• Transplant Program Directors• Organ Transplant Candidates• General Public	E-mail	30 days after the Board of Directors approves the policy

Monitoring and Evaluation by the Department of Evaluation and Quality (DEQ):

The OPTN contractor reviews a sample of medical records during their onsite reviews to verify that the information entered into UNetSM matches the information in the candidate’s medical record, including non-US residents/non-US citizens, during surveys of transplant centers. DEQ staff reviews organ

allocations and makes an inquiry if an organ was not allocated according to the match run sequence. DEQ forwards potential policy violations to the MPSC for review.

Transplant centers are expected to abide by the guidelines set forth in Policy 6.2.1 (Nondiscrimination in Organ Allocation) if they agree to list non-US residents/non-US citizens.

Proposed OPTN Policies:

3.2.1.4 Prohibition for Organ Offers to Non-Members. Members shall not provide organs to non-member transplant centers ~~except to transplant centers in foreign countries as described in Policy 6.4 (Exportation and Importation of Organs – Developmental Status).~~ However, Members may export deceased donor organs to hospitals in foreign countries after having offered these organs to all potential recipients on match runs. Members must submit the organ export verification form to the OPTN contractor prior to exporting deceased donor organs.

6.0 Deceased Donor Organ Transplantation of Non-US Residents/Non-US Citizens, and the Importation of Deceased Donor Organs from Foreign Sources

6.1 Definitions. The following definitions apply to this policy:

6.1.1 Non-US Citizen/US Resident – A person who is not a citizen of the United States, who is present in the United States, and for whom the United States is the primary place of residence.

6.1.2 Non-US Citizen/Non-US Resident – A person who is not a citizen of the United States and for whom the United States is not the primary place of residence.

6.2 Guidelines. Any member transplant center that places a non-US citizen/non-US resident on its waiting list shall adhere to the following guidelines:

6.2.1 Nondiscrimination in Organ Allocation. Selection from the waiting list of non-US citizen/non-US resident candidates for transplantation shall be based on the same allocation policies (Section 3.0) mandated by the Board of Directors for selection of candidates who are citizens or residents. Such selection shall not be influenced by favoritism or discrimination based on political influence, national origin, race, sex, religion, or financial status.

6.2.2 Referrals. Members shall not enter into formal contractual arrangements with foreign agencies or governments for the transplantation of non-US residents/non-US citizens in the United States. Members may negotiate the terms and conditions under which any individual candidate would be treated with the understanding that each candidate must be referred on a case-by-case and physician-to-physician basis.

6.3 Audit and Reporting of Non-US Citizens/Non-US Residents. As a condition of membership, all member transplant centers agree to allow the Ad Hoc International Relations Committee to review and, at its discretion, audit all member transplant center activities pertaining to transplantation of non-US residents/non-US citizens. At member transplant centers where non-US residents/non-US citizens are listed for transplant, the Ad Hoc International Relations Committee shall review the circumstance and justification for listing any non-US resident/non-US citizen traveling to the United States for transplant.

6.3.1 Transparency in Reporting Listings and Transplants of Non-US Citizens/Non-US Residents. The Committee shall prepare and provide public access to an annual

report of member transplant center activities related to the transplantation of non-US citizens/non-US residents.

6.4 Importation of Deceased Donor Organs from Foreign Sources. Members may import deceased donor organs from foreign sources, and in doing so, must adhere to the related policies below.

6.4.1 Formal Deceased Donor Organ Import Agreement. Upon approval by the Board of Directors, a Member may enter into formal, deceased donor organ import agreement with a foreign entity. Each formal agreement cannot exceed two years in duration. A Member that wishes to enter into a formal, deceased donor organ import agreement with a foreign entity must submit a proposal to the Ad Hoc International Relations Committee for review. The proposed deceased donor organ import agreement must:

- 1) Describe the basis for the agreement.
- 2) Describe the expected benefits to the foreign and domestic participants.
- 3) Include credentials of the foreign entity.
- 4) State the number and type of deceased donor organs anticipated for import.
- 5) Outline a plan for reporting the results of the agreement.
- 6) Include a requirement for the donor organization to submit documentation certifying the informed consent of the donor or his or her legal representative.
- 7) 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 US standards for domestic organ procurement.
- 8) Include a requirement for the donor organization to submit documentation of the donor's ABO.

The Ad Hoc International Relations Committee will review each formal agreement every two years.

Each organ imported through a formal agreement must adhere to the requirements listed in 6.4.1.1.

6.4.1.1 Requirements for Importing Deceased Donor Organs through a Formal Agreement. The Member importing any deceased donor organ from a foreign entity must:

- Report the event within 72 hours to the Organ Center.
- Allocate the organ using the Match System, and in accordance with the allocation policy for that organ.
- Provide the minimum required information about the foreign deceased donor organ, as specified in Policies 2 (Minimum Procurement Standards for an Organ Procurement Organization (OPO), 3.5.9 (Minimum Information/ Tissue for Kidney Offer), 3.6.9 (Minimum Information for Liver Offers), 3.7.12 (Minimum Information for Thoracic Organ Offers), and 3.8.2 (Required

Information).

- Comply with the ABO verification requirements in Policies 2 and 3.2.4 (Match System Access).
- Evaluate the organ for transmissible diseases as specified in Policy 4 (Identification of Transmissible Diseases in Organ Recipients).
- Verify that the foreign entity is authorized as a transplant center or organ procurement program by an appropriate agency of its national government.
- Obtain official documentation from the exporting party that it is a medical center authorized to export organs for transplantation.

6.4.2 Ad Hoc Deceased Donor Organ Import. An ad hoc import of a deceased donor organ must meet all the requirements in 6.4.1.1. Except, the Member must notify the Organ Center immediately so that the OPTN contractor can allocate the organ using the Match System, and in accordance with the allocation policy for that organ.

If the Member importing the organ is an OPO, in addition to the requirements listed above, the OPO must provide the following to the OPTN contractor:

- 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;
- Documentation from the donor organization certifying the informed consent of the donor or his or her legal representative; and,
- Documentation from the donor organization verifying the donor's ABO.

The Ad Hoc International Relations Committee will review each Ad Hoc deceased donor import.

~~6.0 TRANSPLANTATION OF NON-RESIDENT ALIENS~~

~~The following policies apply for organ transplantation of non-resident aliens and for importation or exportation of organs for transplantation.~~

~~6.1 DEFINITIONS. The following definitions apply to these policies:~~

~~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.~~

~~6.1.2 **Domestic, American Candidate or Resident Alien.** A domestic, American candidate or resident alien is an individual who is either an American citizen or is an immigrant alien granted permanent resident status by the United States Government or any individual, regardless of immigrant status, qualified for health care entitlement funds from state or federal government sources.~~

~~6.2 GUIDELINES. Any member transplant center which agrees to list non-resident aliens on its Waiting List shall adhere to the following guidelines:~~

~~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.~~

~~6.2.2 **Transplant Centers.** Transplantation of each non-resident alien should be done in a transplant center with a historical pattern of international referral and a reputation for both treatment of primary and endstage organ disease and transplantation, with regard to the particular organ(s) being transplanted.~~

~~6.2.3 **Fees.** Transplantation of non-resident aliens is a humanitarian act and shall not be done for financial advantage. Transplant centers listing non-resident aliens on their Waiting Lists shall charge non-residents the same fees for service as those charged to domestic candidates and recipients.~~

~~6.2.4 **Referrals.** Members shall not enter into formal contractual arrangements with foreign agencies or governments for the transplantation of non-resident aliens. OPTN members may negotiate the terms and conditions under which any individual candidate would be treated with the understanding that each candidate must be referred on a case-by-case and physician-to-physician basis.~~

~~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.~~

~~**6.2.6 Training Programs.** To enhance transplantation in underserved nations, it is desirable for transplant centers engaged in the transplantation of non-resident aliens to establish training programs which include transplantation training of physicians from underserved nations and educational programs designed for development of transplantation services in those underserved nations.~~

~~**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.~~

~~**6.4 EXPORTATION AND IMPORTATION OF ORGANS DEVELOPMENTAL STATUS.** International exchange of organs for transplantation is technically feasible but remains an uncommon procedure. The OPTN regards international sharing of organs to be in an early phase of development.~~

~~**6.4.1 Exportation.** Exportation of organs from the United States or its territories is prohibited unless a well-documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.~~

~~**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.~~

~~**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.~~

~~**6.4.5 Importation.** An imported organ is defined as an organ that is procured outside of the United States of America or its territories. Imported organs must meet the requirements of Policy 6.4.2 (Developmental Protocols in International Organ Exchange) and/or Policy 6.4.3 (Ad Hoc Organ Exchange).~~

~~**6.5 VIOLATIONS OF POLICIES.** Violations of import/export policies (6.2.2 through 6.2.4 and 6.4.1 through 6.4.4) will be reported to the Membership and Professional Standards Committee and may result in suspension of membership by the Board of Directors. Persistent violations of Policy 6.3 (Audit) without justification or explanation, or failure to respond to inquiries will be reported to the Membership and Professional Standards Committee.~~