

**Ad Hoc International Relations Committee Meeting**  
**Thursday, November 7, 2012 Teleconference**  
**3:00pm ET**

The OPTN Ad Hoc International Relations Committee (IRC) convened by teleconference on November 7, 2012 to discuss the following agenda items:

1. The IRC's new liaison introduced herself to members.
2. The Committee reviewed citizenship data submitted since changes to Policy 6.0 were implemented in March 2012. The Chair requested that the committee consider this information and use it to develop a framework for review. The data may guide the IRC in determining what questions are important to ask and what data elements to consider as it develops a format for publically reporting statistics on the transplant on non-resident aliens on an annual basis.

Several years ago the IRC began reviewing OPTN policies related to the transplantation of non-resident aliens. As part of that review they examined the citizenship data being collected. This data is collected on transplant candidates at the time of listing on the Transplant Candidate Registration (TCR) form, on living donors on the living donor registration (LDR) form, and on deceased donors on the deceased donor registration (DDR) form. The categories at that time included US Citizen, Resident Alien, and Non-Resident Alien. The category of non-resident alien was the one referenced in policy. Policy specified a guideline that for each program, less than 5% of deceased donor transplants should go to recipients in that citizenship category.

After review of those categories as they were defined in policy, it was determined that the definitions didn't allow for proper categorization of undocumented non-US citizens living in the US. Additionally, the categories did not allow for the identification of those patients coming to the US specifically for a transplant, and this was the group of patients the committee wanted to better understand.

Based on that discussion, the committee developed new categories for the collection of citizenship data. These categories were implemented in UNet<sup>SM</sup> in March, 2012, and also placed in new policy language that was approved by the OPTN/UNOS Board of Directors in June, 2012.

The new categories for transplant candidates at the time of listing and for living donors are:

- US Citizen (same as previous category)
- Non-US Citizen/US Resident (this is intended to include all persons living in the US regardless of immigration status)
- Non-US Citizen/Non-US Resident (further divided, as noted below)
  - Patient was in the US specifically for the purpose of transplant; or
  - Patient was in the US for reason other than transplant

This information is provided by the transplant center staff filling out the data collection forms in UNet<sup>SM</sup>.

Similar categories were developed for deceased donors, with no subcategories for non-citizen/non-residents.

Data was requested by the committee during its September, 2012 meeting. First, the IRC wanted to see the data being collected to better understand the number of candidates and donors being reported in each of the new categories. Additionally, the policy change implemented this past summer specified that the committee “shall prepare and provide public access to an annual report of Member transplant center activities related to the listings and transplantation of non-US citizens/non-US residents.” It also allows for the committee to request transplant programs with such patients to voluntarily provide additional information about these cases.

As part of the process of developing what that report will include and look like, and to better understand the number of potential cases impacted by a voluntary survey, the IRC needed to see the number of cases that might be included.

All the requested data was queried from March (when the changes were implemented in UNet<sup>SM</sup>) until July, 2012, the most recent period available with relatively complete data. For that five-month period the committee requested data on:

- Waiting list registrations added by organ and citizenship
- Transplants performed by donor type, organ, and citizenship.
- Deceased donors recovered by citizenship; and
- Living donors recovered by organ and citizenship.

#### Waiting List Registrations

During the five month period studied, a total of 23, 564 new registrations were added to the waiting list:

- 92.6% were reported to be US citizens
- 1,058 (4.5%) were reported to be Non-US citizens living in the US
- 135 (0.6%) were reported to not be residents of the US, but were in the country for reasons other than transplant
- 82 (0.3%) waiting list registrations were reported to be in the US specifically related to seeking a transplant
- The highest percentage of new Non-US Citizen/Non-US resident waiting list registrations in the US specifically for the purpose of transplant came from heart-lung registrations at 3.8% (one case) and lung registrations at 0.9% (9 cases).

#### Transplants Performed

The vast majority of recipients transplanted during this five-month period were listed prior to the implementation of the new citizenship categories. It will likely be several years before most transplant recipients have citizenship information reported under the new categories.

From March to July 2012, only 480 (10.3%) of the 4,655 deceased donor kidney transplant recipients were added to the waiting list after the changes in the citizenship category were implemented. For this reason, the 18 deceased donor transplants where the recipient was reported in the US solely for the purpose of transplant is only a small subset of the real total of such transplants during this time period. The remainder of recipients in this category was still reported under the more general heading on “non-resident alien.”

For living donor transplants, 25% of the kidney transplant recipients and 23% of the liver transplant recipients were registered after the implementation of the new citizenship categories.

#### Deceased Donors Recovered

For the 3,480 deceased donors recovered during the same five-month period of review, more than 96% were reported to be US citizens. An additional 102 (2.9%) deceased donors were recovered and reported as non-US citizens living in the US. An additional 15 (0.4%) deceased donors were recovered during this period and reported as not citizens of residents of the US.

#### Living Donors Recovered

For the 2,572 living donors recovered during this five-month period, 94% were reported to be US citizens. Ninety-six additional living donors (3.9%) were reported to be non-US citizens living in the US. A total of 48 living donors recovered during this period were reported as not residents of the US. The majority of these cases (36) were reported to be in the US specifically for the purpose of donation. Additionally, nearly all (45 of the 48) of the living donors reported non-US citizen/non-US resident were living kidney donors.

For comparison purposes, 0.4% of deceased donors were from non-citizen/non-residents as compared to the recipient citizenship of 0.8% of deceased donor transplants. Similarly, 1.3% of living donor transplants reported to be for non-resident recipients compared to 2% of living donors recovered.

Committee members considered the data presented, and posed a number of questions:

- Will the range across programs be provided? Overall data is helpful, but program level data will be more useful.

Staff noted that program-level data was not requested for this particular presentation, and that a larger time period from implementation of the category changes will be necessary to provide meaningful information.

Committee members agreed that a blinded distribution for transplant centers and deceased donors will be helpful for review at the next meeting.

- Why are the numbers so small for intestinal transplant registrations, when this is an organ that non-residents are noted to frequently travel to the US for transplant?

A member was surprised that there were so few intestine registrations in this period from individuals traveling to this country for intestinal or multi-visceral transplant. Staff noted that the number of intestine registrations listed in a month is very small. Time would be expected to provide more clarity with these numbers.

- Look at the age of non-resident recipient. Are parents bringing their children to the US for transplant?

Age will be included in the next iteration of this data for a future meeting.

- What is the country of origin for non-citizen/non-residents? Is transplant available where they reside?

Including this information in the next iteration of this data will be helpful to the committee for consideration.

- Is there a definition for the time period for residency in policy for non-resident aliens?

The current policy does not define the time period. It is self reported. At some point, there may be an opportunity for determining if this is being reported accurately. A member noted that time on the waiting list might be helpful in considering non-citizen/non-residents receiving kidney transplants. This will be included in a future data request. This may be used to look at discrepancies between time waiting and residency. In some cases, individuals may be listed and then return to their home country to await transplant- especially in the case of kidney transplant with longer waiting times in some parts of the country.

- Can registrations be reviewed for active versus inactive status?

The percentage of time spent waiting for a kidney at either status will be helpful when considering non-resident/non-citizen kidney recipients, and perhaps other organs as well if relevant. This will be included in the next data request.

- With the Committee's removal of the 5% audit trigger (when a center's total number of transplants includes more than 5% of non-resident aliens), what should be used as a benchmark to raise concern?

A member noted that it is important to look at the blinded center data on this for a longer period of time before trying to determine a path forward. It is anticipated that many centers will not have any of these transplants. However, if numbers are spread out across the country, it may be possible to look more closely at centers that are a standard deviation above the average. It was noted that the data must be reviewed in a blinded fashion for the IRC to remain objective.

Members agreed that it will be helpful to break down blinded data by region and center if possible. If distribution is broad, then drilling down into specifics for a single program may not be necessary. However, if 1% is spread across 20 programs (as an example), then this would raise concern. Staff noted that numbers are expected to be small, and ranges for each individual program could be calculated within a region. A Committee member noted that many centers are probably still operating under the past 5% rule (though no longer in current policy) from a listing perspective. The changes made by this committee may not be fully recognized to date. This may also impact center behavior.

A Committee member suggested that listing the number of centers falling within a specific category might be useful in communicating the data clearly rather than individual center reporting. For example, if listing for 114 non-citizen/non-residents kidney transplant candidates occurred at 3 centers versus 200 centers, this protects center identity but can be used to identify potential problems.

Staff appreciated the feedback and will prepare data reviewing six months of completed data from the period since implementation of these policy changes, including the additional data elements requested during this call. The Committee will reconvene in January 2013 to consider this new information.

3. The Committee discussed plans for development of the public annual report. The Board of Directors approved policy language that describes this report of transplant activity related to the transplantation of non-US citizen/non-US resident recipients.

Staff noted that if the annual report is released in July, 2013, the report would include the 12 months of data (April 2012 – March 2013). Subsequent reports would then be produced in March when a full calendar year of data became available, with release in April. A second option would involve waiting until March 2014 to produce this report, allowing for a full calendar year of data, including a greater percentage of transplant recipients categorized with the new citizenship definitions. This report would be produced each March for April release. Much of this information is already available by center on the OPTN website, but this report will provide a synopsis in one location.

The Committee agreed that the first report should be released in July (even if noted as preliminary), and then move to the March/April schedule from that point forward.

Concerns were raised that centers should have the opportunity to review their data prior to the release of the report, especially prior to the first release of this report. A member recommended a system similar to what the SRTR does prior to data release. Staff noted that the OPTN is currently not set up to manage the electronic data review process in the same manner that the SRTR uses for this purpose. Staff will need to speak with OPTN leadership to determine the feasibility of meeting this request.

The SRTR representative noted that this might be something that SRTR could assist with, if HRSA was to grant permission. A separate page could be developed to allow centers to review the information as described by the Committee. Speculation was that this could be implemented in time for a month's review prior to release of a July report, and could become part of the OPTN-SRTR annual data report. Staff will discuss this option with OPTN leadership. Several members agreed that review of what could be sensitive numbers is important to the transplant programs, though it was noted that some of the data expected to appear in this report is already available on the OPTN website. Because this is the first time the data will be pulled into one report and highlighted, a member noted that the one month review period will be useful, but may not be necessary on a yearly basis.

The SRTR representative noted that aggregate data might be a more viable option for the report, as presenting small numbers would run the risk of interfering with protected health information that could ultimately be used to identify individuals.

Feedback from OPTN leadership will be shared during the January 2013 conference call.

4. The Chair reported that, due to heavy workloads for both the OPO and Living Donor Committees, the following planned joint committee efforts will be tabled until next year:
  - Define "exhausting the match run;"
  - Substantively revise deceased donor import policy; and
  - Exportation of Living Donor Organs.

5. Staff noted that the timeline for taking the OPTN's policy rewrite effort to the Board of Directors for consideration has been extended. Because another round of public comment will be issued, the IRC now has additional time to complete its review of the proposed plain language updates to Policy 6.0 (Transplantation of Non-Resident Aliens). Staff will provide an updated version of this policy section to the IRC when it is available for review.

**November 8, 2012, Meeting Attendance:**

Marian A. O'Rourke, RN, CCTC	Chair
Charles Alexander, RN, MSN, MBA	Vice Chair
Linda Bowes	At Large
Grace L. Chang, Esq	At Large
Clifford Chin, MD	At Large
Richard S. Luskin, MPA	At Large
Brigette J. Marciniak-Bednar, RN, BSN, CCTC	At Large
Linda Ohler, RN, MSN, CCTC, FAAN	At Large
Scott L. Sanoff, MD, MPH	At Large
Paul J. Volek, MPH	At Large
Gabriel M. Danovich, MD, MB, LRCP, MRCS	Ex Officio
Bertram Kasiske, MD	SRTR
Susan Leppke, MPH	SRTR
Shandie Covington	UNOS Committee Liaison
Sarah Taranto	UNOS Research Liaison
James Alcorn	UNOS
Elizabeth Miller	UNOS