2016 Summary of Non-U.S. Resident Transplant Activity

OPTN Ad Hoc International Relations Committee

Background

During 2010, the OPTN Ad Hoc International Relations Committee (IRC) began reviewing OPTN policies related to the transplantation of non-resident aliens. The review focused on two separate subjects: the categories of citizenship for data collection and the language around the perceived 5% guideline for deceased donor transplantation of non-U.S. residents.

The Committee first examined the citizenship data collected on transplant candidates at the time of listing on the Transplant Candidate Registration (TCR) form, living donors on the Living Donor Registration (LDR) form, and deceased donors on the Deceased Donor Registration (DDR) form. The citizenship categories at that time included:

- U.S. Citizen,
- · Resident Alien, and
- Non-Resident Alien.

OPTN policy specifically referenced the non-resident alien category, specifying a guideline that for each program, if more than 5% of deceased donor transplants went to recipients categorized as non-resident aliens, the IRC could review and audit the program's activity. This traditionally included a letter from the Committee asking for additional details about the program's international activities and local population.

After review of the citizenship categories as they were defined in policy and on the data collection forms, it was determined that the definitions were not uniform and did not allow for the proper categorization of undocumented, non-U.S. citizens living in the United States. Additionally, the categories did not allow for the identification of those patients coming to the U.S. specifically for a transplant – the exact group of patients the Committee wanted to better understand.

Based on their review, the Committee developed new categories for the collection of citizenship data. These categories were implemented in UNetSM in March, 2012 and placed in new policy language that was approved by the OPTN Board of Directors in June, 2012.

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

- U.S. Citizen (same as previous category),
- Non-U.S. Citizen/U.S. Resident (this is intended to include all persons living in the United States regardless of immigration status), and
- Non-U.S. Citizen/Non-U.S. Resident (further divided, as noted below)
 - Traveled to U.S. for Reason Other Than Transplant (patient was in the United States for a reason other than transplant) or
 - Traveled to U.S. for Transplant (patient was in the United States specifically for the purpose of transplant).

Citizenship information is provided by the transplant center staff filling out the data collection forms in UNetSM.

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

Additionally, the Committee examined the Audit policy language in policy 6.3. The policy language at the time specified the following:

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.

This policy allowed the Committee to request additional information from programs with more than 5% of their deceased donor recipients categorized as non-resident aliens. Although the policy never stipulated that a program was not allowed to exceed the 5% threshold, it was widely interpreted as a maximum level allowed by members of the OPTN.

The Committee worked to develop updated language that would not prevent the transplantation of foreign nationals, but rather, enhance the transparency in the listing and transplantation of candidates whose sole intent for being in the United States was to receive this medical procedure. The goal was to be able to identify the scope and practice of travel for transplantation in the United States.

The following is the updated policy language, approved by the OPTN Board of Directors in June, 2012:

17.1.B Review of Non-U.S. Citizens/Non-U.S. Resident Registrations and Transplants

The Ad Hoc International Relations Committee will review all citizenship data reported to the OPTN Contractor. The Ad Hoc International Relations Committee may request that transplant hospitals voluntarily provide additional information about registrations or transplants of non-U.S. citizens/non-U.S. residents.

17.1.C Report of Activities Related to the Transplantation of Non-U.S. Citizens/Non-U.S. Residents

The Ad Hoc International Relations Committee will prepare and provide public access to an annual report of transplant hospital activities related to the registration and transplantation of non-U.S. citizens/non-U.S. residents.

As outlined in Policy 17.1.C, the OPTN Ad Hoc International Relations Committee will prepare and provide public access to an annual report of transplant hospital activities related to the registration and transplantation of non-U.S. citizens/non-U.S. residents. The current report is the Committee's third fulfillment of this policy requirement.

Methods

Two tables are produced for each of the following seven organ groups: kidney, kidney-pancreas, pancreas, liver, intestine, heart, and lung. Unless otherwise noted, data include both pediatric (age 0-17) and adult (age 18+) transplant candidates and recipients.

The first of these tables displays, by transplant center, the number of registrations added to the waiting list during the two most recent calendar years. The total number of registrations added each year is tabulated and, separately, the number of those reported as non-U.S. residents is displayed. Furthermore, the total number of non-U.S. residents is tabulated by whether the candidate is in the U.S. for the purpose of transplant or in the U.S. for other reasons.

The second of these tables displays, by transplant center, the number of deceased donor transplants performed during the two most recent calendar years. This table is set up almost identical to the first

table displaying waiting list additions. The greatest difference in the second table is that some transplants performed during the two most recent calendar years were for recipients added to the waiting list prior to March, 2012. For this reason, the non-resident alien category is displayed in both years.

A third table is provided, only for kidney and liver, that displays, by transplant center, the number of living donor transplants performed during the two most recent calendar years. This table is set up exactly like the second table.

All candidate and recipient citizenship information is based on data provided by the transplant centers on the Transplant Candidate Registration (TCR) form at the time of listing on the waiting list. The revised citizenship categories were implemented in March, 2012.

All analyses in the current report are based on OPTN data as of April 22, 2016.

Results

During 2015, a total of 57,610 adult and pediatric registrations were added to the U.S. solid organ transplant waiting list. Of those, 746 (1.3%) were indicated to be for candidates not residing in the United States, including 321 registrations for candidates in the U.S. specifically for the purpose of transplantation. The percentage of non-U.S. resident registrations added in 2015 varies by organ, from 0.3% (4) of kidney-pancreas registrations to 9.0% (18) of intestine registrations. The 466 kidney and 167 liver additions represent 1.3% and 1.4% of their totals respectively. While 1.2% of adult registrations were non-U.S. residents, 3.4% of pediatric waiting list registrations were for this group of patients.

Approximately 76% (634) of all programs had no registrations added during 2015 where the candidate citizenship was reported as non-U.S. resident. There were 54 programs (29 kidney, 15 liver, 4 heart, 3 lung, 2 intestine, and 1 pancreas) with four or more non-U.S. resident registrations added to the waiting list, and there were 64 programs with at least 5% of their waiting list additions classified as non-U.S. residents (15 kidney, 15 liver, 10 lung, 7 of each intestine and heart, 5 pancreas, 3 kidney-pancreas, and 2 heart-lung).

Across all organs, 95% of programs listed 10 or less non-U.S. resident registrations in 2015, and 75% of programs, with the exception of intestine at 15%, listed two percent or less of their registrations as non-U.S. residents in 2015. Not a single intestine, kidney-pancreas, or pancreas program listed more than 5 non-U.S. resident registrations during the year. One kidney program had 44 registrations reported as non-U.S. residents, the maximum number of non-U.S. resident registrations added at a single liver program was 15, one heart program had 7 such additions, and one lung program had 6. Less than 5% of all programs combined had more than 6.7% of their waiting list additions reported as non-U.S. residents; however, a single kidney program reported that 41.8% of their additions were for such candidates.

Most centers did not have any deceased donor organ recipients during 2015 that were reported as non-U.S. residents. The largest number of recipients reported as non-U.S. residents at a program was 22 for kidney programs and 15 for liver during the year.

Of all living donor transplants performed in 2015, 1.8% (110) were in recipients reported to be non-U.S. residents, and this ranged from 1.7% (96) of kidney transplants to 3.9% (14) of liver.

To obtain a copy of the full report, please submit a data request by completing the online request form at https://optn.transplant.hrsa.gov/data/request-data/.