Ad Hoc International Relations Committee Meeting
Thursday, January 24, 2013 Teleconference
3:00pm ET

The OPTN Ad Hoc International Relations Committee (IRC) reconvened by teleconference on January 24, 2013, to discuss the following agenda items:

1. The Committee received an update on citizenship data submitted since the new candidate categories (US Citizen, Non-US Citizen/US Resident, and Non-US Citizen/Non-US Resident) were implemented in early March, 2012. This data will ultimately be included in an annual report that will provide center-specific information. Specific data that was reviewed to help in the development of this report included:

    - Waiting list registrations added March – October, 2012, by organ, candidate citizenship, age group, and status at listing. Additionally, information on the frequency of non-resident listings across transplant programs.

        - A total of 38,220 waiting list registrations were added during this eight month period:
            - 93.5% were reported as US citizens
            - 1709 (4.5%) were reported to be Non-US citizens living in the US
            - 218 (0.6%) were reported as not residents of the US, but here for a reason for than transplant
            - 130 (0.3%) were reported to be in the US specifically for the purpose of transplantation
            - The highest percentage of new waiting list registrations in the US specifically for the purpose of transplantation came from intestinal registrations (at 4.0% (4 registrations) and heart lung registrations (at 2.8% (1 registration)).
            - *A number of additional data fields were requested as part of this original project. One of these fields is country of origin. While this information is not available now, it will eventually be available when programming is completed.*
            - *A Committee member noted that there might be confusion related to the question of whether a candidate is in the US for transplant. For example, a patient may come to the US with Cholangiocarcinoma or even be diagnosed after arriving, and pursue a transplant at a later date. Concern was raised that listing coordinators receive guidance on how to classify candidates with disease recognized before or after arrival in the US, when a patient may not have come to the US specifically for the reason of transplant. A recommendation was made to review help documentation and the Evaluation Plan related to this field to make sure that coordinators have a clear understanding of what this field means.*
            - *There was great interest in determining why a candidate came to the US- was transplant the primary reason, or was this was an unfortunate incident that happened while here? The reason for coming to the country was noted potentially important in learning why and how long candidates have been here. This information can be collected indirectly now as the system already requests what year a candidate came to the US.*
        - While only 4% of all registrations added during this period represented pediatric candidates, this is the case for 25% of the candidates reported to be in the US specifically for the purpose of transplantation.

- Overall, 78% of registrations were initially in an active status. For those cases where the registrant was in the US specifically for the purpose of transplant, nearly 95% were initially placed in an active status.
- For all organs, more than half of all transplant programs did not list any non-US resident candidates for this eight month period.
    - With the exception of liver and kidney, 75% of programs did not list any US resident candidates during the period.
    - More than 10% of the kidney, intestine, lover and lung programs listed at least one non-US resident candidate during the eight month period.
        - The maximum percentage of such candidates listed at a single program ranged from 5% for simultaneous kidney-pancreas to 200% for one combined heart-lung program.
    - *A committee member requested that this information be broken down by organ more clearly in slides for the committee's review. This was addressed after the meeting. Both absolute numbers and percentages were requested for each organ.*

- Transplants performed March – October, 2012, by organ, donor type, and recipient citizenship

    - Two-thirds of the recipients transplanted during this period were listed prior to the implementation of these new categories. It may take several years before citizenship data using the new categories is available for most kidney transplant recipients due to the size of the waiting list.
    - Of the 7352 deceased donor kidney transplants performed during this time period, only 1010 (13.7%) were added to the waiting list after the updated citizenship categories. For this reason, the 33 total deceased donor transplants where the recipient was reportedly in the US for the purpose of transplantation is only a small subset of the real total of such transplants during this period, with the remainder still reported under the heading of "non-resident alien."
        - *It was noted that a total 0.7% is the total overall percent of transplants completed during this time period for non-US citizens based upon the new, more precise citizenship categories and the previous non-resident alien classification.*
        - *A request for transplant centers to update citizenship for candidates listed prior to the March 2012 citizenship category updates was recommended by a committee member. This was never outlined in the public comment proposal, and will not be pursued due to the significant burden it would put on transplant programs, especially larger ones. Some of this information may be difficult to obtain. Additionally, there is no policy to enforce the request of such information. Members agreed that such a request would be expected to trigger a great deal of pushback from the transplant community.*
    - For living donor transplants during this same eight month period, 34% of the kidney transplants and 39% of the liver transplants were registered after the new categories were implemented.

- Deceased donors recovered March – October, 2012, by donor citizenship

- More than 96% of all deceased donors were reported to be US Citizens. (Please note the categories vary slightly from recipient to donor, as deceased donors would not be in the US for the purpose of transplant).
- Additionally, 3.2% (174) deceased donors were recovered and reported to be non-US Citizens living in the US
- Twenty-one (0.4%) deceased donors were recovered during this period and reported as not living in the US.
    - *It was noted that this data category is probably of the greatest interest to the committee at this point, noting that the older non-resident alien category will be problematic in clearly understanding these numbers.*
    - *Members were asked to carefully review the data tables in the meeting materials packet, which demonstrated all organ types.*

- Living donors recovered March – October, 2012, by organ and donor citizenship

    - About 94% of all living donors recovered during this eight month period were reported to be US citizens
    - An additional 3.6% (142) of living donors were reported to be non-US citizens living in the US
    - Eighty living donors recovered during this same period were reported as not residing in the US.
        - The majority of these cases (57) were reported to be in the US specifically for the purpose of transplantation/donation.
        - Nearly all (76 of the 80) were living kidney donors.

2. The Committee reviewed a draft list of pros and cons developed by staff based upon discussion during the November 8, 2012, conference call regarding where to locate the annual report under development to share the center-specific data shared above. Staff asked Committee members to consider the following points when reviewing the pros and cons:
    - What is absolutely necessary?
    - What do you absolutely want to avoid.

    Several members noted that they liked the idea of the citizenship information included as part of the Scientific Registry of Transplant Recipients' (SRTR) annual data report tables. They believe that this adds to overall transparency in reporting. It was also noted that providing an aggregate annual report with the ability to take ownership of the data and manage it (i.e. time to review prior to release as is done with the SRTR's program specific reports) would be desirable. This would be a hybrid of the latter two options listed.

    The Committee's feedback will be shared with OPTN and SRTR leadership and then taken to a joint project officers meeting (POM) at HRSA. This will be a new contractual consideration that HRSA will have to address. Ultimately, HRSA will consider feedback from this committee, UNOS and SRTR to make a determination on the path forward regarding where the annual report will reside.

    Members discussed concerns that though this information is already available by center on the OPTN website, inclusion on SRTR reports will be more visible. All were cautioned to put politics aside when considering the issue and to focus on presenting data in a way that it can be easily cataloged and considered. It was noted that this should be looked at as a

publication of statistics. There is not annual report to the Membership and Professional Standards Committee and the 5% flag to represent concern that a program has what is perceived to be a high number of non-US citizen/non-US resident recipients no longer exist. Policy 6.3 (Review and Reporting of Non-US Citizen/ Non-US Resident Listings and Transplants) indicates that the committee will review data and may request that member transplant centers voluntarily provide additional information about listings or transplants of this population.

Committee members were asked to carefully review the pros/cons list and provide feedback, not specifically selecting an option- but providing thought on must haves and absolutes to avoid in determining a path forward. This information was requested by February 7, 2013, in order to collate feedback for presentation at the Joint POM.

An SRTR representative noted that not all data are editable within the program specific reports. Only those elements that go into the risk adjustment model may be adjusted by a center prior to release. As a result the type of data the Committee would like to include related to citizenship would not be editable based upon the SRTR's current programming for this part of its website.

The Ethics Committee Chair, a guest at this meeting, noted that the most important issue is that this data is available and transparent. This is critical in order to be meaningful to both programs and the general public.

A Committee member questioned whether feedback should be sought from the Executive Committee or Board of Directors regarding how to frame the report. The Committee's thoughts could be shared with the Executive Committee and then approval or additional feedback could be requested in order to avoid any surprises. Another member noted that Policy 6.3.1 (Transparency in Reporting Listings and Transplants of Non-US Citizens/Non-US Residents.) requires the committee to provide public access to an annual report of member transplant center activities, not report directly to the Board. By passing this language, the Board has already authorized the Committee to create this annual report.

Committee members were reminded to submit feedback to staff regarding their thoughts on the location of the annual report. The Committee will reconvene to review data and hear the outcome of the Joint POM meeting in the spring. Once the annual report format is determined, the Committee will turn its attention to the development of a voluntary survey to collect additional information about listings or transplants of non-US citizens/non-US residents.

January 24, 2013, Meeting Attendance:

Marian A. O'Rourke, RN, CCTC	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
Jorge Reyes, MD	At Large
Gene Ridolfi, BA, RN, MHA	At Large
Scott L. Sanoff, MD, MPH	At Large
Anthony Sebastian, MD, FRCS, FACS	At Large
Paul J. Volek, MPH	At Large
Gabriel M. Danovich, MD, MB, LRCP, MRCS	Ex Officio
James Bowman, MD	HRSA Ex Officio
Bernard Kozlovsky, MD, MS	HRSA Ex Officio
Tabitha Leighton	SRTR
Jon Snyder, PhD, MS	SRTR
Alexandra Glazier	Ethics Committee Chair, guest
Shandie Covington	UNOS Committee Liaison
Sarah Taranto	UNOS Research Liaison
Elizabeth Miller	UNOS