OPTN/UNOS Ad Hoc International Relations Committee
Report to the Board of Directors
June 23-24, 2014
Richmond, VA

Marian O'Rourke, RN, Chair
Jorge Reyes, MD, Vice Chair

Contents

Action Items **2**
Committee Projects **2**
1. Define Exhausting the Match Run 2
2. Review Deceased Donor Import Policy 3
Committee Projects Pending Implementation **5**
Implemented Committee Projects **5**
Review of Public Comment Proposals **5**
Other Committee Work **6**
3. IRC Annual Report Subcommittee* 6
4. IRC Voluntary Survey on Listings and Transplants of Non-US Citizens/Non-US Residents 8
5. IRC Review of Formal Import Agreements 9
Meeting Summaries **9**

*Please click **here** to access the 2014 Report of Non-U.S. Resident Transplant Activity

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This report reflects the work of the OPTN/UNOS Ad Hoc International Relations Committee during the period 1/21/2014-5/7/2014.

Action Items

None

Committee Projects

1. Define Exhausting the Match Run

Public Comment: *March, 2015 (Estimated)*
Board Review: *November, 2015 (Estimated)*

OPTN policy currently states that members may export deceased donor organs to hospitals in foreign countries only after offering the organs to all potential recipients on the match run. Members must submit the *Organ Export Verification Form* to the OPTN Contractor prior to exporting deceased donor organs. The joint subcommittee is tasked with defining the level of effort an OPO must expend in making organ offers to all nationally listed patients in the US before offering an organ outside of the US for transplant. In a previous proposal to revise this section of policy, the IRC and Ethics Committees made non-substantive changes to the export policy language. The changes were not acceptable to Region 10, AOPO, or the OPO Committee because the proposed changes did not concretely define what it means for an OPO to exhaust a match run before pursuing exportation of organs outside of the US. The subcommittee is studying the issue to propose solutions to assist the transplant community in identifying the specific circumstances which must be present to indicate that allocation cannot be completed in the US and organs can be offered outside of the US. The goal is to recognize organs as a national resource and prevent organ wastage under defined circumstances.

The IRC joint subcommittee met via conference call on February 3, 2014 to review the issues as understood by the Committee leadership and UNOS staff in an attempt to identify the overall problem(s) to be addressed by the subcommittee. Concerns were presented and discussed from the perspective of the OPO, the Transplant Program, and the OPTN.

Subcommittee members identified the following issues:

- Overall length of the match run versus the amount of time the OPO has to make a decision regarding alternate allocation
- When and how an OPO would meet the documentation requirements of the policy
- Verification requirements for determining level of OPO effort in finding a suitable recipient on the match run
- Premature 'exhaustion of the match run' may result in missed offers resulting in decreased transplant options for patients

- Attempting to 'exhaust the match run' may cause an organ to become non-viable for many candidates leading to organ discards

During the call, the subcommittee reviewed data on the number and types of organs exported out of the US since 2010 **(Exhibit A).** It was noted that most of the exported organs were thoracic organs where cold ischemic time plays a larger factor in the ability to allocate organs over long distances. Additionally, while not collected in the OPTN database, OPO members indicated that in their experience, the organs exported out of the country have gone to Canada. A review of exported organs made ten years ago by the Ad Hoc International Relations Committee showed similar results. The subcommittee also discussed various challenges in specific regions which make placement efforts even more challenging.

During discussion, the subcommittee narrowed the problem statement to the concern that literal interpretation of the policy is cumbersome and time-consuming, potentially leading to organ discard and wastage. The subcommittee requested data in an attempt to identify some array of *where* in the match sequence placement efforts would be futile. The data request will examine at what point on the match, are organs rarely, if ever, accepted by a US transplant program and for those organs that were exported, how far down the match offers were documented.

The subcommittee determined a need to review additional data to help inform their path forward. Some of the questions raised by the subcommittee included:

1. At what point on the match, are organs rarely, if ever, accepted by a US transplant program?
2. For those organs that were exported, how far down the match were offers documented?

The subcommittee will review the data at its next meeting.

2. <u>Review Deceased Donor Import Policy</u>

Public Comment: *March, 2015 (Estimated)*
Board Review: *November, 2015 (Estimated)*

During the 2012 rewrite of the previous OPTN Policy 6.0, the issue was raised regarding the placement process for offers of deceased donor organs recovered outside of the US.[1] OPTN policy states that the OPTN member (Host OPO) is responsible for allocating deceased donor organs recovered outside of the US without a formal agreement (ad hoc organ import). However, it is also in policy and in current practice that the OPTN has the responsibility for facilitating placement of deceased donor organs recovered outside of the US. The manual allocation process used by the Organ Center to facilitate foreign organ imports does not allow for enforcement or monitoring of OPTN policy requirements placed on domestic organ transplants. For example, ABO subtyping, infectious disease testing, laboratory certifications/approvals, informed consent, declaration of death, etc. The OPTN process for foreign organ placements requires a substantial expenditure of Organ Center resources, though the annual organ yield from these placement attempts is very low. Although this OPTN ad hoc organ import allocation algorithm is not specified in OPTN

[1] Policy 6 was moved to Policy 16 in the 2013 plain language rewrite of the policies.

policy, it does not appear to be prohibited by either NOTA or the Final Rule. Clarification of the entity responsible for placement of ad hoc foreign organ imports is necessary to ensure compliance with OPTN policy requirements, potentially increasing the safety and efficiency in placement for these organs.

The IRC Joint Subcommittee to Review Deceased Donor Import Policy met by teleconference call on February 10, 2014 to:

1. Develop a common understanding of the issues surrounding the current import policy
2. Attempt to define the problem(s)
3. Discuss and propose options for a path forward

The background provided to the subcommittee included an explanation of the origination of the issue, description of the two types of organ import exchanges the subcommittee would be reviewing (formal and ad hoc), references to import data from 2010-2013, and a brief overview and historical framework of the process the UNOS Organ Center uses to place imported organs recovered outside of the US under an ad hoc organ exchange.

The subcommittee was also provided with a brief history of previous IRC Committee efforts to address ad hoc international organ exchanges, which included proposed policy modifications and attempts for Canadian adoption of the DonorNet® utility or a similar electronic system. The subcommittee was advised that neither effort was successful. Subcommittee discussion also focused on examining ways to improve ad hoc exchanges using Canada as a model. The goal would be to establish the framework/template for these organs to become a legitimate potential source of organs coming into the DSA and help incentivize the establishment of formal agreements for placement of these organs. It was determined that the important areas of focus for the subcommittee at this time would be ensuring the safety of these organs and improving the efficiency of placement efforts.

During its meeting on March 10, 2014, the IRC was briefly updated on the work of the subcommittee. Members inquired about the process used to place imported organs recovered outside of the US (mostly thoracic organs from Canada) under a formal agreement versus an ad hoc organ exchange and differences between the two types of placements. It was noted that organs are imported to the US only when Canada has exhausted the candidates on its own match run. These organs tend to be of more marginal quality or harder to place due to small size or ABO incompatibility. Further, geographic distance is often a hindering factor as it may be quicker to place an organ in a bordering US state rather than another Canadian province.

Under a formal import agreement, an OPO will use a foreign country as its local recovery area. There are currently two OPOs with formal organ import agreements. The New England Organ Bank serves as the OPO for Bermuda, and Lifelink of Florida serves as the OPO for the Bahamas. Because neither country has its own OPO, when an organ becomes available it is treated as a local donor with samples imported and testing conducted in the US in the standard manner outlined in OPTN policy. It was noted that the number of organs resulting from these agreements is minimal, averaging about 3-4 annually. Alternately, foreign agencies without an agreement sometimes contact the OPTN Contractor to allocate organs. Under these ad hoc import exchanges, the UNOS Organ Center serves in the role of the OPO for the placement of these organs which may require 2-3 hours to complete the initial data entry prior to beginning allocation. In such cases, the OPTN currently offers the organ nationally, using the U.S. hospital closest to the offering foreign agency as the "donor

hospital". The OPTN Contractor uses a national version of the match run to complete this task. The match run generated in these instances is modified from what an OPO would see if it were to offer the organ.

The primary differences between Canadian ad hoc exchanges and the formal exchanges in the Bahamas and Bermuda were discussed. Instead of one national system, Canada has a series of provincial systems with differences between the provinces. Also, in the case of the Bermuda and Bahamas agreements, the U.S. OPOs use those countries as their local donor service area because they do not have their own OPOs. However, the Canadian provinces do have the equivalent of a local OPO; therefore, the transition between a Canadian and a US OPO with regard to placement efforts, could also be an area of challenge.

The IRC was also updated on internal discussions underway at UNOS to help clarify whether the OPTN should continue to facilitate these foreign placements (with the process codified in policy as an OPTN function). It was noted that this request will be brought to the Executive Committee of the OPTN Board of Directors to help inform the current path of the subcommittee. If the Executive Committee endorses the process as a documented OPTN function, the policy language would be updated to clarify its role with regard to foreign import placements and address existing gaps in the import policy.

On May 7, 2014, the IRC leadership presented a request to the Executive Committee to determine whether foreign organ placements, a task currently being conducted by the OPTN, should be codified in policy as an OPTN function **(Exhibit B)**. Lack of clear responsibility for the OPTN policy requirements associated with importing foreign organs, has hindered efforts to revise the policy to ensure imported organs meet OPTN requirements. Public comment feedback from the OPO community has indicated that OPO's are practically and logistically unable to do the work to ensure these protections are in place. Therefore, clarification of the entity responsible for placement of ad hoc foreign organ imports is necessary to address compliance with OPTN policy requirements, potentially increasing the safety and utilization of these organs. As the OPTN is already placing these organs, the IRC requested the Executive Committee to endorse its efforts to formally assign this responsibility to the OPTN.

Following the presentation, the Executive Committee unanimously supported the request from the IRC. With this endorsement, the IRC will begin policy development work to research, study, and propose solutions to help bridge the gap between Canadian and OPTN policy requirements, potentially improving the efficiency of the placement process and maximizing utilization of imported organs.

Committee Projects Pending Implementation

None

Implemented Committee Projects

None

Review of Public Comment Proposals

None

Other Committee Work

3. IRC Annual Report Subcommittee*

During 2010, the Ad Hoc International Relations Committee (IRC) began reviewing OPTN policies related to the transplantation of non-resident aliens. The review included a study of the categories of citizenship for data collection and the language surrounding the perceived 5% threshold for deceased donor transplantation of non-US residents. At the time, OPTN policy specified that 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. Programs selected for audit received a letter from the Committee requesting additional details about the programs' international activities and local population.

The Committee examined the citizenship data collected on the OPTN data collection forms and the existing citizenship categories as they were defined in policy. Based on the review, the Committee developed new categories for the collection of citizenship data which were implemented in UNet℠ in March, 2012 and appeared in new policy language 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:

- US Citizen (same as previous category)
- 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

The original 5% audit policy never stipulated that a program could not exceed 5% of transplants to this group; however, it was widely interpreted as a maximum level allowed by members of the OPTN. The language was not intended to prevent the transplantation of foreign nationals, but rather, enhance the transparency in the listing and transplantation of candidates whose sole purpose for entering the United States was to receive a transplant. The goal was to be able to identify the scope and practice of travel for transplantation in the United States. To provide transparency with regard to this group, the policy language approved in June, 2012 also specified that the Committee would prepare and provide public access to an annual report of member transplant center activities related to the listings and transplantation of non-US citizen/non-US residents. The IRC annual report subcommittee was formed to provide guidance in developing the content and format of the report.

During its March 10th and May 1st meetings, the Committee was updated on subcommittee progress toward implementation of the annual report and presentation to the Board of Directors during its June 23-24, 2014 meeting. The annual report subcommittee met via conference call on January 21, 2014 and April 9, 2014 to review and discuss the presentation of the summary data tables and accompanying narratives for the draft report. Subcommittee members also provided feedback and reviewed drafts via e-mail. In January, the subcommittee viewed the proposed format for the report using liver data. It was explained that the descriptive tables in the report will contain full year information for 2013 with no conclusions drawn from the data. The tables will display three different citizenship categories for patients transplanted during each year. This is because the transplants that occurred during the reporting timeframe were for patients added to the waiting list prior to the establishment of the new categories. For patients listed in 2013, there are only two

categories. In January, the subcommittee recommended several modifications to the report, including:

- An additional column showing the sum of the three categories which would group together the non-residents historically reviewed by the IRC under its 5% audit policy, with an accompanying narrative explaining the presence of data containing the previous citizenship category descriptions.
- Alphabetical presentation of transplant center codes.
- Inclusion of the citizenship of living donors and recipients that received a living donor organ by region for transparency.
- Reordering of certain tables in the report for improved flow and continuity.
- Modification of certain tables to show the total of non-residents for consistency with the transplant table.
- Distribution of all transplant programs for each organ.
- Number of transplant programs with 0, 1, or 2 transplants (shown as an X Y chart).
- Summary table for each organ stratified by adult versus pediatric candidates.

On April 9, 2014, the subcommittee reviewed the updated draft report that incorporated changes from the subcommittee call and feedback submitted via e-mail. The changes included substantive edits to the report as well as cosmetic changes to the tables to help clarify, simplify, and provide transparency to the data.

Some changes to the report included:

- Additional formatting was added to some of the tables to show consistent capitalization and punctuation in the headings.
- A column heading for 2013 was modified to clarify that the table contained both the non-US resident category as well as the old non-resident alien category.
- The organ categories shown in each table were reordered to match the data order shown throughout the report.
- A graphic was added showing a breakout of the citizenship of adult and pediatric registrations added in 2013.
- To simplify information previously reported, figures were updated to show waiting list additions where at least 5% were classified as non-US residents
- New figures were added to show the distribution of the counts of non-US resident registrations added by program as well as the percentages for registrations.
- Figures showing the number and percent of non-resident waiting list additions were updated to report the data from largest to smallest instead of from smallest to largest, showing each program as a single bar.

During the review, additional changes were recommended. It was recommended that language be developed explaining, because the percentages reported were very low, that the axes on several of the figures did not start at zero. UNOS Research staff suggested adding another figure only showing the percentage of interest so that the range in data could be seen without the distorted axis. A Committee member also suggested that the background section in the report eliminate the reference to transplant tourism. It was noted that the question about transplant tourism occurring in the US was never posed to the Committee as an area of interest or inquiry. It was determined that the reference would be removed to better reflect the intent of the Committee.

During the May 1st meeting of the IRC, the Committee was presented with an overall summary of the report with a description of the data tables by section. The Committee was informed that the background section contained a summary of Committee work since 2010 revising policy language, the methods section contained a summary of the reporting time period, explanation of the presence of the previous citizenship categories in the tables, and a reference to the source of the data. The results section is separated into an overall section which summarizes information for all organ types, and a section reporting information for each organ type with descriptive text summarizing each table. In each of the organ specific sections, the data is provided by region and the individual program specific information is provided under each specific organ type. It was noted that combined heart-lung transplants were not reported as there were no transplants performed or waiting list registrations added during 2013 for non-U.S. residents.

Brief data highlights from the report included the following:

- 4% of programs with at least 1 waiting list registration added in 2013 had 4 or more additions that were for non-US residents.
- Non-US resident waiting list additions comprised 2.5% of all pediatric registrations in 2013 versus 1% of adult registrations.
- 39 of the 819 transplant programs with at least 1 waiting list addition during 2013 had 5% or more of their registrations added for non-US residents.
- 81% (666) of transplant programs with at least 1 waiting list addition during 2013 didn't have any registrations added for non-US residents.
- In 2013, 1% of deceased donor transplants went to non-US residents.
- Of deceased donor transplants performed during 2013, intestine programs saw the largest percentage of transplants performed in non-US residents, at 8%.

The path forward section was reviewed with members to demonstrate future work with the report moving forward. A suggestion was made to add a figure in the report with deceased donor transplant and waiting list data plotted on a regional map to illustrate the distribution geographically. The intent would be to give more understanding of the density and flow of the patient population with a visual reference. Members also briefly discussed changes that could be incorporated into future reports, including a graphic demonstrating the impact of the non-US residents on the US transplant system, point of origin information such as country of residence, and ratio of listings to transplants. A member of the Committee also inquired about the possibility of filtering information in the tables to allow easier examination of the fields that contain data versus those that do not.

Following some additional brief discussion, Committee members present on the call agreed upon consensus that the annual report **(Exhibit C)** should be released for presentation to the Board with the recommended additions. **Please click here to access Exhibit C.**

4. IRC Voluntary Survey on Listings and Transplants of Non-US Citizens/Non-US Residents

As part of its 2010 review of policy language, the IRC Committee examined the audit policy language requiring all member transplant centers to allow the Ad Hoc International Relations Committee to review and audit all transplant program activities pertaining to the transplantation of non-resident aliens, where non-resident alien recipients constitute more than 5% of recipients of any particular type of deceased organ. Revisions to the policy language removed the 5% audit requirement, instead allowing the Ad Hoc International

Relations Committee to review all citizenship data reported to the OPTN through distribution of a voluntary survey of registrations and transplants of non-US citizens/non-US residents.

During its March meeting, the IRC was briefly updated on the status of the voluntary survey. The intent of the survey is to collect information to better understand the situations under which these types of transplants occur. The challenge for the IRC will be identifying a threshold within which transplant programs meeting certain criteria would be surveyed. However, at this point in time, the Committee has not come to any conclusions about the threshold for surveying transplant programs, nor the questions to be asked. It was noted that the proposed voluntary survey would be distinguished from the previous audit survey by its focus on individual patient level data as opposed to program specific data. The IRC will begin work on the survey soon now that the database contains one full year of data collection under the new citizenship categories, drawing upon a previous list of potential survey questions developed by the IRC as a starting point.

5. **IRC Review of Formal Import Agreements**

During its March meeting, the Committee briefly discussed the formal deceased donor organ import agreements. OPTN Policy 17.2.A requires IRC review and subsequent Board approval of the formal organ exchange agreements every two years; however, this has not occurred in some time. Once the IRC has determined the approximate timetable for completion of the import policy review, it will decide whether or not review of the formal organ exchange agreements should take priority as a stand-alone project, or is able to occur in tandem with the import policy clarifications.

Meeting Summaries

The Committee held meetings on the following dates:

- March 10, 2014
- May 1, 2014

Meetings summaries for this Committee are available on the OPTN website at:
http://optn.transplant.hrsa.gov/members/committeesDetail.asp?ID=6

United Network for Organ Sharing
Deceased Donor Organs Exported Out of the U.S. January, 2010-October, 2013

	Organ												Total	
	Heart		Intestine		Kidney		Liver		Lung		Pancreas			
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Year														
2010	20	30.8	1	50.0	1	25.0	4	40.0	15	19.5	3	60.0	44	27.0
2011	18	27.7	1	50.0	0	0	3	30.0	11	14.3	2	40.0	35	21.5
2012	18	27.7	0	0	2	50.0	2	20.0	24	31.2	0	0	46	28.2
2013	9	13.8	0	0	1	25.0	1	10.0	27	35.1	0	0	38	23.3
Total	65	100.0	2	100.0	4	100.0	10	100.0	77	100.0	5	100.0	163	100.0
Region of Recovering OPO														
1	3	4.6	0	0	0	0	0	0	0	0	0	0	3	1.8
2	2	3.1	0	0	2	50.0	2	20.0	3	3.9	0	0	9	5.5
3	1	1.5	0	0	1	25.0	0	0	0	0	0	0	2	1.2
5	24	36.9	0	0	0	0	1	10.0	38	49.4	0	0	63	38.7
6	27	41.5	1	50.0	0	0	4	40.0	18	23.4	2	40.0	52	31.9
8	0	0	0	0	0	0	1	10.0	4	5.2	0	0	5	3.1
9	1	1.5	1	50.0	0	0	1	10.0	2	2.6	2	40.0	7	4.3
10	7	10.8	0	0	1	25.0	1	10.0	12	15.6	0	0	21	12.9
11	0	0	0	0	0	0	0	0	0	0	1	20.0	1	0.6
Total	65	100.0	2	100.0	4	100.0	10	100.0	77	100.0	5	100.0	163	100.0
Donor Age														
< 1	6	9.2	1	50.0	2	50.0	3	30.0	2	2.6	1	20.0	15	9.2
1-5	13	20.0	1	50.0	0	0	3	30.0	0	0	2	40.0	19	11.7
6-10	8	12.3	0	0	0	0	0	0	4	5.2	0	0	12	7.4
11-17	5	7.7	0	0	1	25.0	0	0	5	6.5	0	0	11	6.7
18-34	14	21.5	0	0	0	0	0	0	11	14.3	1	20.0	26	16.0
35-49	11	16.9	0	0	1	25.0	1	10.0	22	28.6	1	20.0	36	22.1
50-64	8	12.3	0	0	0	0	1	10.0	14	18.2	0	0	23	14.1
65+	0	0	0	0	0	0	2	20.0	19	24.7	0	0	21	12.9
Total	65	100.0	2	100.0	4	100.0	10	100.0	77	100.0	5	100.0	163	100.0
Final Disposition														
Organ Exported and Confirmed Transplanted	65	100.0	2	100.0	4	100.0	9	90.0	74	96.1	2	40.0	156	95.7
Organ Exported, Not Transplanted	0	0	0	0	0	0	1	10.0	3	3.9	3	60.0	7	4.3
Total	65	100.0	2	100.0	4	100.0	10	100.0	77	100.0	5	100.0	163	100.0

Based on OPTN data as of January 24, 2014
Data subject to change based on future data submission or correction.

OPTN Ad Hoc International Relations Committee (IRC)
Joint Subcommittee to Review Deceased Donor Import Policy

Jorge Reyes, MD
Vice Chair/Subcommittee Chairman

OPTN

UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

The Problem:

Conflicting OPTN policy and practice with regard to allocation of ad hoc foreign organ imports.

OPTN

UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

The Background:

- OPTN Policy gives the OPTN Member (Host OPO) responsibility for allocating deceased donor organs.
- However, current policy gives the OPTN (Organ Center) responsibility for placing deceased donor organs recovered outside of the US without a formal agreement. (Policy 17.2.C.)
- Although this placement process is not codified in OPTN policy, it does not appear to be prohibited by either NOTA or the Final Rule.

OPTN

UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

Consequences:

- Process does not allow for enforcement or monitoring of OPTN requirements; presenting a potential patient safety risk.
- Process not well known by the transplant community; lacks transparency.
- Process consumes considerable Organ Center resources, though the organ yield is low.

OPTN

UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

Request:

Endorse IRC policy development assigning responsibility for allocation of ad hoc deceased donor organ imports to the OPTN

- **Policy language to be developed giving the OPTN authority to serve in the role of an OPO in ad hoc foreign organ exchanges.**
- **Subsequent IRC policy development to address patient safety protections; vet the current placement process for transparency and improved efficiency.**

OPTN

UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

June 2008 IRC Policy Proposal

Concepts Addressed:

- Legitimacy of the offering foreign organization
- Laboratory testing and safety of the organ
- Member application of OPTN policy concerning ethical practices in an organ import event.

Public Comment Themes:

- OPTN, not members, should certify foreign agencies that export organs to a US OPO or transplant center;
- OPTN should certify Canadian OPOs;
- Unfair burden on members to verify the legitimacy of foreign agencies exporting organs;
- Impact of policy modifications on import/export of Canadian organs;

OPTN

UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

Expected Outcomes:

Confirmation of patient safety protections provided under OPTN policy

More definition, structure and consistency in ad hoc foreign placements

Potentially increase annual # of organ placements to US candidates

OPTN

UNOS DONATE LIFE
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