OPTN/UNOS Ad Hoc International Relations Committee Meeting Minutes December 14, 2017 Teleconference

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Introduction

The Ad Hoc International Relations Committee (AHIRC) met by teleconference on 12/14/2017 to discuss the following agenda items:

1. Proposed Region 9 Organ Sharing Agreement

The following is a summary of the Committee's discussions.

1. Proposed Region 9 Organ Sharing Agreement

Summary of Discussion:

Background Information

UNOS staff presented an overview of the current policies addressing the importation of deceased donor organs. *OPTN Policy 17.2: Importation of Deceased Donor Organs from Foreign Sources* allows for the importation of deceased donor organs from foreign sources, either with or without a formal agreement. This policy also outlines the requirements for submitting a formal agreement for approval and the requirements for importing an organ with or without a formal agreement. Currently, there are only two formal agreements in effect, both focused on OPOs providing donor recovery services to neighboring island countries (Bahamas and Bermuda). UNOS staff noted that organs procured under those agreements are allocated according to organ allocation policies.

UNOS staff also provided an overview of the current process used to import organs without a formal agreement. The current process is outlined below:

- The Canadian OPO coordinator (ZCAN) contacts the Organ Center (OC)
- OC staff will fax or email the placement request form to the ZCAN coordinator to gather donor data
- ZCAN coordinator completes the form and sends back to the OC, along with the ABO source documentation
- Organ Center staff enters information into DonorNet® donor summary faxed to ZCAN coordinator to verify data entry and ABO
- Organ Center staff receives signed documentation, runs match, then sends electronic offers.
- For match runs, the Organ Center uses the closest US donor hospital to the Canadian donor. For example, the closest donor hospital to Quebec City is located in Bangor, Maine
- ZCAN match runs are unique:
 - o Thoracic Organs no DSA, start at Zone A from nearest US hospital
 - o Abdominal Organs no DSA, no region, one combined national match run
- Case set-up time ranges from 30 minutes to several hours.

UNOS staff noted that several issues need to be considered by the Committee as they review the proposal:

 Geography – Is this proposed agreement the right approach due to ongoing OPTN discussions about geography?

- Equitable access Is this agreement counter to the current discussions about equitable access to organs according to organ-specific allocation policies?
- Are there additional data needed by the Committee to make an informed decision?

Finally, UNOS staff noted that this agreement does not follow the same approval process as a variance. The main difference being an agreement does not go through the normal policy development process which includes collaboration between multiple committees as well as public comment. UNOS staff also noted that no agreements have been submitted since *Policy 17: International Organ Transplantation* was changed several years ago.

Overview of Proposed Region 9 Agreement

The representatives from Region 9 provided an overview of the problems they are trying to address with this agreement. These include:

- No organs from Quebec have been transplanted in the US in several years
- Process takes too long for the type of constraints in the donor process in Quebec
- Language barriers
- Translation of records
- Phone calls from remote locations
- Transferring patients from smaller centers to recovery centers

The representatives from Region 9 have been working with Quebec Transplant to identify ways to more quickly gauge interest in an organ so they can decide whether to continue pursuing donation. This process is similar to the system currently in place in Region 9 for imported offers from other regions of the United State. Currently, if an organ offer comes in, there is a centralized phone number staffed by LiveOnNY on behalf of all the transplant programs in New York State. The offer is sent out electronically through a web application ("web app") to gauge interest in the import offer from all transplant centers in Region 9. In the previous five years of using the app, there is a response rate of less than 15 minutes for all the programs that received offers. If there is interest in the organ, the ZCAN match will be generated by the Organ Center in order to begin allocation. Once the centers are identified, the candidates at those centers will be identified on the match run. All other non-Region 9 candidates would be bypassed using the appropriate bypass code and the organs allocated according to the match run to Region 9 transplant centers.

The Region 9 representatives noted that if this pilot is successful with Quebec Transplant, it could be implemented on a national basis.

Committee Discussion

One Committee member asked if Quebec Transplant has tried working with the Organ Center to address the challenges they are having while trying to export organs. UNOS staff noted that the OPOs in Toronto and Vancouver have had success with the current process. What is different about Quebec Transplant that would justify the need for this agreement? The Region 9 representative's response was that it is difficult for Quebec Transplant to collect the information, have the back and forth communications, and then determine if there is enough interest to move forward with donation. UNOS staff reminded the Committee that once the required information is available, the Organ Center can execute a match run and identify potential recipients within a reasonable amount of time if the Canadian OPO is familiar with the process. One Committee member mentioned that a potential first step would be to help Quebec Transplant better understand the process since part of issue they have with the current process is on their end.

The Committee discussed one of the rationales for the agreement being that Region 9 is at a geographic disadvantage with Canada to the north and the Atlantic Ocean to the east. One Committee member noted that this is also a challenge for other areas of the United States. Additionally, there have been a lot of OPTN discussions about geography and equitable access organs within organ allocation systems. One Committee member noted that this proposal would

preferentially steer organ offers into Region 9 which runs counter to the direction of organ allocation policy in the country.

Several Committee members expressed support for this pilot program as a step forward to optimize the relationship with Canada. One Committee member opined that increasing the dialogue with Canada to increase the number of organ offers that are imported and exported could benefit both counties. Another Committee member expressed support for innovative approaches to increase the number of organs available. This proposal is clearly benefits a specific geographic region and the Committee would need to discuss how this agreement might be perceived by the rest of the country.

Conclusion/Next Steps

Several Committee members expressed support for this agreement as an innovative approach to increase the number of organs imported from Canada. The Committee would like to better understand the timeline and how the allocations would actually work for each organ type. The Committee will also recommend that the rationale for the agreement focus on an "innovative pilot program" instead of using geography and a deficit in organs exported versus imported as the justification. Once the agreement has been modified, the Committee can better identify the next steps to make a decision on the agreement.

Upcoming Meeting

• Conference Call - TBD