OPTN/UNOS Pediatric Transplantation Committee
Meeting Summary
December 21, 2016
Conference Call

William Mahle, M.D., Chair
George Mazariegos, M.D., Vice Chair

Discussions of the full committee on December 21, 2016 are summarized below. All committee meeting summaries are available at *https://optn.transplant.hrsa.gov*.

Other Significant Items

1. OPTN/UNOS Board of Directors Update

The Vice Chair provided an update to the Pediatric Committee following the OPTN/UNOS Board of Directors meeting in St. Louis, MO (December 5-6, 2016). Due to travel conflict with the Chair, the Vice Chair attended the meeting on behalf of the Pediatric Committee. A handful of elements were prominent during this meeting:

- Chair Breakfast – Time allowed the Chair Breakfast for Q&A with the OPTN President and Vice President. Numerous other OPTN committee leaders were in attendance and the dialog was very informative. This included a round table discussion on new project ideas, and committee rosters/anticipated member vacancies. The Vice Chair spoke to the group about the two projects currently in development by the Pediatric that are aligned with Goal III of the OPTN Strategic Plan (Reduce Pediatric Liver Waiting List Mortality and Tracking Outcomes Post-Transition)
- Liver Re-districting Update – The Chair of the Liver and Intestine Committee updated the Board on the Liver Re-districting during the open session. Notable in this discussion was the deadline imposed by the Board of December 2017.
- Adult Heart Allocation proposal – The proposal from the Thoracic Committee on Adult Heart Allocation was approved by the Board. The Pediatric Committee previously provided feedback on this proposal. The Vice Chair of the Thoracic Committee did a great job presenting a complex proposal.

2. Non Resident Transplant Activity – Ad-hoc International Relations Committee (AHIRC)

The Vice Chair of the Ad-hoc International Relations Committee (AHIRC), presented an update on the 2015 Transplant Activity Report. Historically, changes to OPTN Policy 17 in 2012 added new data elements to TIEDI® forms to capture citizenship of candidates, as well as create an annual report on the transplant activity of non-citizens/non-residents of the U.S. The AHIRC is evaluating trends to see if there are specific regions/centers that have a larger percentage than others. The AHIRC noted:

- No difference between the percentage of non-U.S. citizens or residents registered for an organ transplant and those transplanted.
- The number of non-U.S. citizens or residents registered for an organ transplant and those transplants performed is extremely low, but this number has increased in the last three years.
- 75% of transplant programs in the U.S. have not registered a non-U.S. citizen or resident.

- Two countries of residence comprise the highest number of non-U.S. citizens or residents transplant candidates – Kuwait and Saudi Arabia.

The Committee held a discussion following the presentation. The Committee acknowledged the number of cases of is small and members raised concern whether the data included deceased donor transplants (e.g.: a non-U.S. citizen or resident came to the U.S. to get a transplant), or if the data included living donor transplants (e.g.: someone who comes to the U.S. with an identified living donor). The Vice Chair of AHIRC noted the data reflects both types of transplants. Further, he commented the AHIRC is sensitive to the concern that transplants on non-U.S. citizens or residents may appear to take organs away from U.S. citizens. The charge from the OPTN/UNOS Board of Directors was to examine the data and report if an issue was detected. The small numbers would suggest this is not a serious issue and the AHIRC will continue to examine this question.

The Committee also briefly discussed the historical role the 10%, then 5% threshold for maximum allowable transplants played in non-U.S. citizens or residents program-level decision making. By exceeding this threshold, a transplant program would be subject to an OPTN audit. Members noted that low volume transplants, including some pediatric transplants, could easily exceed this threshold. Members of the Committee felt it was a positive step to remove this threshold from OPTN Policy 17.

Though the overall number of non-U.S. citizen or resident transplant activity is small, some Committee members did raise concern over one transplant program with the highest volume of non-U.S. citizen or resident candidate registrations and transplants during the period 2013-2015 [data presented with redaction]. Members noted this transplant program is performing a majority of their pediatric liver transplants in non-U.S. citizens or residents. The Vice Chair of AHIRC confirmed the accuracy of this information for the Committee. Further, he clarified this transplant program could be a large adult liver transplant program and the number reflects high volume adult candidates and a small volume of pediatric candidates. However, it is still true that the majority of pediatric liver transplants at this hospital were in non-U.S. citizen or resident candidates that came to the U.S. for the expressed purpose of transplantation. The Pediatric Committee requested AHIRC to examine the question if inappropriate levels non-U.S. citizen or resident transplantation activity are possible.

One member did express concern about the number of non-U.S. citizens or residents presenting at their program with metabolic liver disease. Further, they asked if these patients with metabolic disease could potentially get liver transplants ahead of chronic liver disease candidates (who have a higher mortality rate)? The Vice Chair of AHIRC responded that there is a certain granularity to the data and he will suggest AHIRC look at the data by diagnosis.

Next Steps:

- The Pediatric Committee requested The Vice Chair of AHIRC share the Ethics Committee's response to the AHIRC presentation.
- The Pediatric Committee requested AHIRC to examine the question if inappropriate levels non-U.S. citizen or resident transplantation activity are possible.
- The Pediatric Committee wants to continue to follow this issue and appreciated the Vice Chair's presentation on behalf of the AHIRC.

3. Update from Transition Working Group

The Chair of the Transition Working Group, updated the Committee on the status of the new project idea *Tracking Pediatric Transplant Outcomes Following Transition to Adult Transplant Programs*. The Committee identified this new project during brainstorming in October 2015 and the concept has progressed through the development process. Discussions with the Transition Working Group on November 29, 2017 noted that "lost to follow-up" designation for recipients impacts long term recipient follow-up data. This problem was supported by OPTN data in heart, liver, and kidney transplants, most significantly in kidney transplant recipients after transition to adult care. Based on the data and discussions with the Working Group, a guidance document appears to be an ideal approach to addressing the problem.

This project is expected to have impact on Goals III (Improve Waitlisted Patient, Living Donor, and Transplant Recipient Outcomes) and V (Promote the Efficiency of the OPTN). The goal is this project it to increase capture of follow-up data on pediatric recipients after transition to adult care. Work done by the Living Donor Committee to increase follow-up on living donors can likely be translational in the current project.

The Committee discussed the project after the presentation. Members inquired, would the focus of the guidance be only on kidney recipients, or all organ recipients? The Working Group Chair noted that the issue appears to be more prevalent in kidney recipients after transition. The guidance would likely be general in some aspects, and organ-specific in others; including the two cohorts of recipients with the highest rates of lost to follow-up designation. Another question arose about the need for additional data. The Working Group Chair responded that additional data requests *could* be needed, thought she thought a large data request would be unlikely. One instrument that would be informative would be a survey of pediatric transplant programs with low lost to follow-up rates in order to learn effective practices.

The Committee voted (9-Yes, 0-No, 0-Abstain) to request review by the OPTN/UNOS Policy Oversight Committee (POC) during their new project review in January 18, 2017. The Vice Chair will present this project to POC and address any questions/concerns during the conference call. Updates will be provided to the Pediatric Committee at a future call in January 2017. The target for this project is consideration by the OPTN/UNOS Board of Directors in December 2017.

With no further business to discuss, the meeting was adjourned.

Upcoming Meetings

- February 15, 2017 4:00-5:00 PM Eastern (conference call)
- March 15, 2017 4:00-5:00 PM Eastern (conference call)
- April 21, 2017 10:00 AM-4:00 PM Eastern (Chicago, IL)
- May 17, 2017, 4:00-5:00 PM Eastern (conference call)
- June 21, 2017 4:00-5:00 PM Eastern (conference call)