

**OPTN/UNOS Pediatric Transplantation Committee**  
**Meeting Minutes**  
**January 18, 2017**  
**Conference Call**

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

**Introduction**

The Pediatric Transplantation Committee met via teleconference on January 18, 2017 to discuss the following agenda items:

1. Update from MPSC/Pediatric Working Group
2. Update from POC Committee review of Pediatric Transition Project
3. Review of New Project Ideas

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

**1. Update from MPSC/Pediatric Working Group**

The Chair provided an update from the MPSC/Pediatric Working Group that has been working on amendments to the Pediatric Emergency Membership Exception pathway.

Summary of discussion:

The Committee previously heard an update from this inter-committee working group in October 2016. Since that time, the Working Group has met by conference call twice to iron out remaining details of the proposed pathway. At the conclusion of the Working Group's call in December 2016, members felt the group's charge was fulfilled.

The Chair briefed the Committee on the elements of the pathway for heart and liver transplant programs that wanted to register a pediatric candidate without obtaining approval for a pediatric component. The intent of the Working Group was to be relatively strict, but have allowance for how medicine is practiced around the U.S.

*Heart candidate –*

The patient meets one of the following conditions: is pediatric Status 1A according to Policy 6: Allocation of Heart and Heart-Lungs

- Has a surgically implanted, non-endovascular Ventricular Assist Device (VAD) that is not approved for use outside the hospital by the U.S. Food and Drug Administration.
- Is on Extracorporeal Membrane Oxygenator (ECMO).

The primary transplant physician or primary transplant surgeon at a transplant program with an approved pediatric heart component verifies the medical judgment that transport to a heart transplant program with an approved pediatric component is not advisable for this patient.

The Chair commented that two devices that would likely meet the first bullet point were from HeartMate or Heartware. With regard to ECMO, there is the possibility of transporting patients. However this capability is not universally available.

*Liver candidate –*

The patient qualifies for and is registered as a pediatric status 1A as outlined in OPTN Policy 9.1.B. The patient cannot qualify by status 1A exception.

The primary transplant physician or primary transplant surgeon at a transplant program with an active pediatric liver component agrees that it is not medically advisable to transport this patient to a liver transplant program with an approved pediatric component.

*For both pediatric heart and liver transplant candidates:*

If the candidate no longer meets these criteria, the transplant program must remove the candidate from the wait list within 24 hours and may not transplant the candidate. The transplant program must provide information to the candidate on transfer to a transplant program with an approved pediatric component. If requested, the transplant program must assist the candidate with transfer.

The Chair then profiled a graphic to illustrate the handling process for the Committee. After sharing this profile, the Chair reviewed the project timeline with the Committee with the following target dates:

- Discussion with Liver & Intestine, and Thoracic Committees in March/April 2017
- Consideration for public comment on April 21, 2017
- Public comment on July 31, 2017
- Post-public comment review in October 2017
- Board consideration on December 4, 2017

The Chair commented that he feels this project has been progressing quite well. Members of the Committee were in general agreement with the progress to-date.

Next steps:

- The Committee will review specific bylaw language for the Pediatric Emergency Membership Exception pathway during the next conference call on February 15, 2016.

## **2. Update from POC Committee review of Pediatric Transition Project**

The Vice Chair updated the Committee on the discussions from the OPTN/UNOS Policy Oversight Committee (POC) call earlier in the day.

Summary of discussion:

This new project has been in development since the fall of 2016. In December 2016, the Committee felt this project was appropriately developed (problem statement, alignment with strategic plan, and high-level solution) and unanimously supported consideration by the POC. The POC met by conference call today and discussed this project. Comments that came up in the POC discussions were favorable. The Vice Chair indicated that some questions about what were the *real* issues...was this an operational issue or an outcomes issue? The Vice Chair explained that understanding transplant outcomes is challenged by the logistical issues faced by recipients. The POC concurred with the Working Group's assessment that this project was in alignment with Goal III of the OPTN Strategic Plan and unanimously approved the project. This is a key first-step for this project. A subsequent review by the OPTN/UNOS Executive Committee will take place on January 19, 2017. If approved by this body, the Committee will have formal approval to begin further work on the project.

UNOS staff echoed the Vice Chair's comments about the sequential review by the Executive Committee. Further, UNOS staff advised the Committee to diligently consider collaboration with stakeholders in two distinct groups; 1) those critical stakeholders during the development of the proposal, and 2) those interested stakeholders whose comments should be sought during public comment.

Next steps:

- Conference calls will be held with the Transition Working Group in the coming months. The Chair of the Working Group will update the Committee as the proposal progresses.

The Chair segued to a discussion on the catalog of potential projects.

### **3. Review of New Project Ideas**

#### Summary of discussion:

The Chair shared that it was important for the Committee to always consider new project ideas and reviewing the current project catalog to ensure relevancy. He briefly profiled the concepts for project ideas for the Committee. The list has been developed over time with the last brainstorming session coordinated in 2016.

The Committee had a discussion on two project ideas:

#### *Promoting Living Donation*

The Committee felt it was important to promote living donation to pediatric candidates. A prior review of data in March 2016 noted declines historically in living liver and kidney donation to pediatric candidates. Members of the Committee mentioned the role of altruistic organ donation and the potential for collaboration with the Ethics Committee on a white paper. One member agreed this was important, noting that a sensitive approach should be advised. It was her opinion that transplant programs could sensitively and diligently explore this manner of donation. This effort would be a nice complement to ongoing public discussions on altruistic organ donation.

A member mentioned that obtaining data to help describe the problem would inform future discussions for the Committee. Other members shared support for the comment and one asked, is there data on pediatric transplant outcomes who have been transplanted from living donors? Despite the lengthy discussions historically, there is little understanding *why* living donation to pediatric candidates has declined. An off-shoot of this project could be *why* there have been declines in living donation, especially to children. If the Committee is able to understand *why*, they can better develop strategies to solve the problem. Other members verbalized their support for the comments and asked if data could be obtained on the current utilization of living donor organs in pediatric candidates.

The Committee also discussed the need to message this project carefully, that a “way to help sick children” could be one consideration. The Vice Chair agreed, noting this idea could synchronize with the current on-hold liver project. Further, he did feel there was a substantive amount of work here to be a stand-alone project.

The consensus of the Committee was this is an important issue. UNOS staff shared that caution needed to be exercised in this area. It was outside the scope of the OPTN to fully *promote* living donation. A different way of looking at this could be pursued, e.g.: the Living Donor Committee’s project to Reduce Disincentives to Living Donation.

#### *Using Increased Risk Donor Organs*

The Chair commented that this project could be central to reducing waiting time and expanding the donor pool for pediatric transplant candidates. He asked the members on the call for their thoughts on the topic. One member commented that it may be challenging to ask the pediatric transplant community to consider using increased risk organs when some pediatric organs are declined for pediatric candidates, only to be successfully transplanted in an adult candidate. Similarly, it would be difficult to ask for more access for adult organs for pediatric candidates when organs from pediatric donors are not used in pediatric candidates. The Vice Chair agreed with these comments, noting there may be a need to address optimizing current donors before

looking at expanding to increased risk donors. The Chair also agreed, noting that occasionally pediatric hearts are transplanted into less acutely ill candidates, or not transplanted at all. A member shared that many of the turn down issues are size issues [donor/potential recipient size mismatch], but sometimes the reasons are rather nebulous. Other members verbalized her support for these comments. Additionally, one member reported that she has conducted some research in organ turn-downs and found wide variability in reasons why organs are declined.

Several members of the Committee indicated that more data would be needed to understand this issue. The ROOT report is provided to centers with aggregate data on offers for the last month. A member pointed out the transplant programs are not held accountable and the full report is not publically available. She believes the MPSC should be engaged to use this report in considering program performance. The Chair cautioned about using this data in a punitive fashion; a quality improvement angle would be better received. The Vice Chair asked, can we review this data in aggregate during a future call? He continued to state that it would be useful to see national and regional data about pediatric organs that are declined to pediatric recipients that are later transplanted into adult recipients. Further, looking at organ specific data would be informative. This will help people understand the issues before people think about increased risk donors.

Based on the discussion, the Chair summarized that there appeared to be substantial interest in examining data on organs that were declined but transplanted with good results in candidates lower on a match run list. UNOS staff on the call indicated that they would look into this data and report back to the Committee during a future call or meeting. The HRSA liaison to the Committee suggested that the Committee reach out to the Kidney and Liver & Intestine Committees to see what data may have been requested for their on-going projects.

#### Next steps:

- UNOS staff will investigate the potential for a call with leadership of the Living Donor Committee to discuss *Reduce Disincentives to Living Donation*.
- UNOS staff will look at data on the current utilization of living donor organs in pediatric candidates and report back to the Committee.
- The Chair will perform a literature review on organ turn-downs and report back to the Committee.
- UNOS staff will look at past data requests for relevant data.
- The Chair asked committee members to submit their new project ideas to UNOS staff.
- New project brainstorming will take place in April 2017.

With no further business to discuss, the conference call 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)