

OPTN/UNOS Pediatric Transplantation Committee
Meeting Minutes
January 17, 2018
Conference Call

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

Introduction

The Pediatric Transplantation Committee met via teleconference on January 17, 2018 to discuss the following agenda items:

1. Overview of new Executive Committee concept document - *Improving OPTN Committee Structure*
2. OPTN Board Meeting Q&A
3. Update on proposal to *Reduce Pediatric Liver Waitlist Mortality*
4. Update on Kidney Committee's proposal to *Improve Access to Pediatric and Highly Sensitized Kidney Candidates*

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

1. Overview of new Executive Committee concept document - *Improving OPTN Committee Structure*

UNOS staff provided a high level introduction to a new concept document from the OPTN/UNOS Executive Committee.

Summary of discussion:

The Chair previously asked UNOS staff and the Vice Chair to profile a forthcoming concept document from the OPTN. This concept document introduces a new approach to OPTN committees. UNOS staff provide a synopsis of the concept's historical development and goals of the proposal.

In June 2016, OPTN/UNOS Executive Committee endorsed formation of a workgroup to assess the OPTN/UNOS committee structure. The charge of this working group was to identify possible improvements to committee recruitment, selection, and engagement, and how to improve committee alignment with the Board. After endorsing several new changes to improve the committee recruitment process, the Executive Committee is considering a new concept recommended by the committee governance workgroup with regard to improving the committee governance structure.

The committee governance workgroup identified the current "one size fits all" structure as needing improvement because it limits opportunity for broader transplant community participation and makes it difficult to incorporate diverse perspectives on committees. In addition, the structure and current methods for collecting public comment from committees, regions, societies, and the general public does not allow the Board of Directors to fully consider the sentiment of particular groups or communities when making policy decisions, as perspectives are offered sporadically throughout the system.

Neither the National Organ Transplant Act nor the Final Rule mandate a committee system. The committee-approach greatly strengthens the organization by helping achieve its mission and strategic goals. This is accomplished by providing advice to the Board and each other in the policy development process and through completion of certain tasks.

The current committee structure serves the OPTN well in terms of providing organ-specific and other specialty expertise. However, it does not allow for the flexibility to ensure diverse perspectives from different types of transplant and donation professionals or from the patient and donor population. The committee governance workgroup determined that a structure with greater flexibility would allow for more diverse perspectives and, along with a new way of collecting public comment, would allow the Board to understand and consider the sentiment and level of buy-in from different stakeholders.

Based on current need, the Executive Committee endorsed initially revising the current structure into two types of groups:

- Subject committees: organ-specific or other groups where broad policy development is required. These groups will be tasked with developing organ-specific policies, policies that span across organs, and/or those that cannot be accomplished through the work of another group.
- Expert councils: groups with a perspective that is needed on three or more subject committees.

UNOS staff then described the timeline for project development, including:

- February 21, 2018 – presentation during a full Committee conference call
- March 2018 - written response from the Pediatric Committee to the Executive Committee
- April-July 2018 – the formal proposal is drafted by the Executive Committee
- August – October 2018 – Public comment will be sought on the proposal (another opportunity for the Pediatric Committee to review amendments and comment)
- December 2018 – Board consideration

Members held a brief discussion following the presentation. Generally speaking, members supported the goals of the project and recognized the current structure of OPTN committees is not optimal. One of the current weaknesses is the lack of pediatric representatives on all of the organ specific committees. However, members were very concerned that changing the standing of the Committee to an “expert council” would substantially demote and dilute the pediatric perspective within the OPTN. There are distinct and separate pediatric allocation rules for the OPTN and the need to have a strong pediatric perspective on these proposals was clear. The central concern is that a pediatric expert council would lack the ability to put forth proposals to improve pediatric transplantation. Members expressed optimism that a potential future state for the pediatric community through the OPTN may involve both a pediatric subject committee and pediatric expert council.

UNOS staff thanked the Committee for their feedback at this early stage. The comments will be shared with OPTN leadership and the Executive Committee.

Next steps:

The Committee will have an opportunity to hear a formal proposal on the concept document during their February 2018 conference call. A subsequent public comment period regarding a formal proposal from the OPTN will follow in August 2018.

2. OPTN Board Meeting Q&A

UNOS staff briefly profiled the actions taken by the OPTN/UNOS Board of Directors during the December 2017 meeting.

Summary of discussion:

UNOS staff had previously updated the Committee on the events of the OPTN/UNOS Board of Directors Meeting in December 2017. The Committee's proposal to *Revise Pediatric Emergency Membership Exception* was one of the proposals approved at this meeting. Thirteen other proposals were approved, and one proposal was declined.

One member commented the Pancreas Committee proposal garnered some support during development. However, there was concern shared by the Committee, OPTN regions, and others in the transplant community of the potential for detrimental impact on pediatric kidney transplantation. Members felt this impact may be more prominently seen in donation services areas (DSAs) that had an active kidney/pancreas transplant program.

UNOS staff reported the next Board meeting will be in June 2018 in Richmond, VA. The Vice Chair will be attending the meeting to represent the Committee.

Next steps:

UNOS staff will update the Committee following future Board meetings.

3. Update on proposal to Reduce Pediatric Liver Waitlist Mortality

UNOS staff and the Vice Chair updated the Committee on a project under development by the OPTN/UNOS Kidney Transplantation Committee.

Summary of discussion:

This proposal from the Committee has been "on-hold" for the past year due to the large effort to address *Enhance Liver Distribution*. The Vice Chair approached the OPTN/UNOS Policy Oversight Committee (POC) on November 17, 2017 with a request to transition to "evidence gathering". The POC agreed with alignment with Goal 3 of the OPTN Strategic Plan (Improve waitlisted patient, living donor, and transplant recipient outcomes). POC members felt focusing on the most at-risk pediatric candidates was consistent with Goal 3. However, a project focusing on all candidates < 18 y/o was consistent with Goal 2. At the conclusion of the discussion, the POC voted the project was in alignment with Goal 3, and unanimously to move forward to Executive Committee with the recommendation to approve the project.

UNOS staff then explained that a short delay in the consideration by the Executive Committee was possible due to two unexpected Board actions in December 2017 that would consume resources and UNOS staff limitations due to medical leave. The Executive Committee is anticipated to consideration on this project in February or March 2018. If approved, the Pediatric Committee can proceed with the development of this proposal.

Members thanked UNOS staff for the update and expressed disappointment over the continued delays in getting project approval. They verbalized the lengthy time over which this concept was put forth and the continued waitlist mortality of pediatric liver transplant candidates. Some member shared their position that many of these instances of waitlist mortality were likely preventable. Members supported generating a memo to the Executive Committee to express the desire to move forward on this project.

Next steps:

Committee leadership will draft a memo to relay supporting information on the project and submit to the Executive Committee in the coming weeks.

UNOS staff will provide updates on this project during a future conference call.

4. Update on Kidney Committee's proposal to Improve Access to Pediatric and Highly Sensitized Kidney Candidates

UNOS staff updated the Committee on a developing project from the OPTN/UNOS Kidney Transplantation Committee.

Summary of discussion:

In October and November 2017, the Committee had discussions on potential shortcomings in the Kidney Allocation System (KAS). One of the chief concerns was the lack of increase in pediatric kidney transplant rates as compared to trends seen in adult kidney transplant rates. The Kidney Committee had contemporaneously shared concerns similar to these, as well as identified other opportunities for improvements to KAS. The Kidney Committee is putting forth a proposal to the POC to address the two highest priority areas; 1) improve access for highly sensitized kidney candidates, and 2) improve pediatric kidney transplant access. UNOS staff shared hypothesized solutions from the project:

- Using different indices for kidney quality for child and adolescent donors
- Allocation classification changes
- Prioritize pediatrics as much as the highly sensitized (or certain threshold of highly sensitized)
- Better longevity matching
- Allocate on donor age for pediatrics rather than KDPI
- Extra points for every month on list
- Children stratified with other children

The Kidney Committee has expressed the desire to have a joint workgroup with the Committee once the project was approved. This workgroup was well supported by Committee members with seven members offered to participate.

The Vice Chair shared that the POC was scheduled to discuss this project from the Kidney Committee during their conference call today [January 17, 2018]. Due to time limitations on the call, this new project will be discussed during the February 16, 2018 POC call.

The Vice Chair then opened the floor for discussion. Members verbalized frustration with the project development to-date. This included, 1) the sentiment that the optimal committee to sponsor a pediatric-focused proposal impacting kidney transplantation was the Pediatric Committee, not the Kidney Committee, 2) the belief that the current state of the project idea did not reflect good collaboration between the Kidney and Pediatric Committee. UNOS staff shared that new projects are customarily developed by one committee *before* initial POC consideration. There are frequently discussions during this time with leadership of stakeholder committees to inform and assess for support. Workgroups involving other stakeholder committees are only formed *after* POC and Executive Committee approval. UNOS staff shared that responsibility to modify or enhance KAS falls on the Kidney Committee as they were the sponsoring committee of the index proposal that was approved in 2013.

Members then discussed the pros and cons of independently sponsoring a proposal to improve pediatric kidney transplant access. UNOS staff indicated that this was a possibility. However, the Committee had committed to a work flow of projects that would fully occupy it's time for the foreseeable future. This includes:

- Board-Approved Projects Pending Implementation:
 - *2015 Training and Experience Requirements for Key Personnel at Pediatric Transplant Programs* (this includes the recent modifications to the Pediatric Emergency Membership Exception pathways)

- Projects in Evidence Gathering (a.k.a. active development):
 - *Tracking Pediatric Transplant Outcomes Following Transition*
- Projects On-Hold and Seeking Approval:
 - *Reduce Pediatric Liver Waiting List Mortality*

The implications of the Committee sponsoring the a project on pediatric kidney transplant access in lieu of the Kidney Committee are that work on this project would not commence for at least two years if adhering to the above mentioned work plan. By allowing the Kidney Committee to sponsor the project, both of the Committee's highest priorities (pediatric liver and kidney transplantation) would be addressed appropriately and in the shortest amount of time. Members on the call verbalized understanding of this perspective.

At the conclusion of the discussion, the Vice Chair and UNOS staff committed to initiating a dialog with leadership of the Kidney Committee. The goals of this dialog would be to discuss the concerns brought up by my members and endorse robust collaboration going forward. Members agreed with this approach, and thanked the Vice Chair for his transparency and continued communication efforts between the Committee and POC.

Next steps:

UNOS staff will identify a date and time for leadership of the Pediatric and Kidney Committees to discuss concerns and a plan for future collaboration on the project.

UNOS staff will distribute a PDF of the Kidney Committee's project form to the Committee for review.

With no other business to discuss, the conference call was adjourned.

Upcoming Meetings

- February 21, 2018 4-5 PM Eastern (full committee conference call)
- March 21, 2018 4-5 PM Eastern (full committee conference call)
- April 19, 2018 9-3 Central (Chicago, IL)
- May 16, 2018 4-5 PM Eastern (full committee conference call)
- June 20, 2018 4-5 PM Eastern (full committee conference call)

Attendance

- **Committee Members**
 - George Mazariegos, M.D. – Vice Chair
 - Khashayar Vakili, M.D. – Region 1
 - Rachel Ryan, RN, B.S.N., CCTC – Region 2
 - Priya Verghese, M.D., M.P.H. – Region 7
 - Arika Hoffman, M.D. – Region 8
 - Kishore Iyer, M.B.B.S., FRCS, FACS – Region 9
 - Dean Kim, M.D. – Region 10
 - Andrew Savage, M.D. – Region 11
 - Sharon Bartosh, M.D. – At-large
 - Evelyn Hsu, M.D. – At-large
 - Margaret Knight, RN, M.S.N., CRNP – At-large
 - Melissa McQueen – At-large
 - Melissa Nugent, RN, B.S.N., CCRN, CCTC – At-large
 - John Renz, M.D., Ph.D. – At-large
- **HRSA Representatives**
 - James Bowman, M.D.
 - Marilyn Levi
- **SRTR Staff**
 - Jodi Smith, M.D.
- **OPTN/UNOS Staff**
 - Christopher L. Wholley, M.S.A.
 - Kimberly Combs
 - Amanda Robinson
- **Other Attendees**
 - Kimberly Harbur- visiting Board member