OPTN/UNOS Pediatric Transplantation Committee
Meeting Minutes
February 15, 2017
Conference Call

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

Introduction

The Pediatric Committee met via teleconference on February 15, 2017 to discuss the following agenda items:

1. Revisions to the Pediatric Emergency Membership Exception Pathway
2. Public Comment Proposal - Improving Allocation of En-Bloc Kidneys
3. Request for Feedback - Remove Disincentives for Living Donation

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

1. Revisions to the Pediatric Emergency Membership Exception Pathway

The Chair provided an update to the Committee on the project to amend language for the Pediatric Emergency Membership Exception Pathway.

Summary of discussion:

The Chair provided a brief recap of the last discussion on the topic from January 18, 2017. Prior comments from the Committee were favorable, with members acknowledging the simplicity of the proposal. The purpose of the discussion today was to review the proposed bylaw language that arose from the Working Group in recent months. UNOS staff then shared the proposed bylaw language changes for heart and liver transplant programs that may wish to transplant a transplant candidate less than 18 years old.

Heart Transplant Programs:

An ~~designated~~ active heart transplant program that does not have a pediatric component may register a patient less than 18 years old on the waiting list if *all* the following conditions are met:

~~1. The transplant program believes it must transplant the pediatric patient to prevent a serious and imminent threat to the patient's health or safety~~

~~2.~~ 1. The patient meets one of the following conditions: ~~is pediatric Status 1A according to *Policy 6: Allocation of Heart and Heart-Lungs*~~

   a. 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.

   b. Is on Extracorporeal Membrane Oxygenator (ECMO).

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

If the candidate no longer meets these criteria, the transplant program must remove the candidate from their waiting 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 transplant program must submit a pediatric membership exception request to the OPTN Contractor within 72 hours of the candidate's registration on the waiting list.~~

~~The MPSC will retrospectively review pediatric membership exception requests. As part of this review, the MPSC will consult with the Pediatric Transplantation Committee. In submitting the pediatric membership exception request, the transplant program must demonstrate *all* the following:~~

1. ~~That the transplant was necessary to prevent a serious and imminent threat to the patient's health or safety~~
2. ~~That it was medically inadvisable or commercially impractical for the transplant program to transport the candidate to a designated heart transplant program with an approved pediatric component~~
3. ~~The candidate was registered as pediatric Status 1A and remained pediatric Status 1A until the time of transplant~~

~~If the member fails to demonstrate the criteria for this emergency exception, any listing made thereunder will be a violation of OPTN obligations and will be referred to the MPSC.~~

Liver Transplant Programs:

A designated liver transplant program that does not have a pediatric component may register a patient less than 18 years old on the waiting list if *both* of the following conditions are met:

~~1. The transplant program believes it must transplant the pediatric patient to prevent a serious and imminent threat to the patient's health or safety~~
~~2. The patient is pediatric Status 1A according to *Policy 9: Allocation of Livers and Liver-Intestines*.~~

1. The patient is registered as a pediatric status 1A according to OPTN *Policy 9.1.B: Pediatric Status 1A Requirements*. This does not include a patient who qualifies by status 1A exception.

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

If at any time the candidate no longer meets these criteria, the transplant hospital must remove the candidate from their waiting 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 transplant program must submit a pediatric membership exception request to the OPTN Contractor within 72 hours of the candidate's registration on the waiting list.~~

~~The MPSC will retrospectively review pediatric membership exception requests. As part of this review, the MPSC will consult with the Pediatric Transplantation Committee. In submitting the pediatric membership exception request, the transplant program must demonstrate *all* the following:~~

~~4. That the transplant was necessary to prevent a serious and imminent threat to the patient's health or safety~~
~~5. That it was medically inadvisable or commercially impractical for the transplant program to transport the candidate to a designated liver transplant program with an approved pediatric component~~
~~6. The candidate was registered as pediatric Status 1A and remained pediatric Status 1A until the time of transplant~~

~~If the member fails to demonstrate the criteria for this emergency exception, any listing made thereunder will be a violation of OPTN obligations and will be referred to the MPSC.~~

The Chair thanked UNOS staff for the overview of the language and opened the floor for discussion. Several members of the Committee felt the language was well written and straight forward. One member noted, the language appears to read that the listing hospital needs to *provide the transfer* to a pediatric hospital if they no longer meet the requirements of the pathway. Is there any anticipation for push-back from adult transplant programs to assist with transfers? UNOS staff responded that the influence for this language was drawn from other areas of OPTN policies and bylaws; patients need to be notified of their acceptance or denial of transplant listing by the transplant program. Further, if a scenario of a waiting time transfer presents, the index transplant program must assist with the transfer of the candidate's waiting time. The Working Group's concern was to prevent a candidate listed and removed by an adult transplant program being left to "fend for themselves" after removal. It would not mean the adult program was compelled to help with the logistics of a transfer. Rather, the adult program should be engaged with this transfer. After a brief discussion, several members of the Committee felt it may be best to remove this content to avoid confusion over a process that transplant programs have been historically able to work through without significant challenges.

Another Committee member asked, why are candidates on Extracorporeal Membrane Oxygenator (ECMO) included on the list for heart transplant programs? The Chair responded that patient transport on ECMO is not universally available at all hospitals. If a pediatric hospital is contacted for a consult regarding the ability to transport a patient on ECMO, it is within the purview of that pediatric hospital to disagree with the adult hospital regarding the inability for transport and accept the patient for transfer. This second step can function as a safety check whether a patient can be transported. The Chair felt this highlighted the need to educate key personnel at pediatric programs that many of these candidates could be transported. That said, the use of this Emergency Membership Exception Pathway is anticipated to be a rare event.

Following the Committee's discussion, UNOS staff outlined the timeline for the proposal:

- March 2017 – Solicit feedback from the OPTN/UNOS Thoracic and Liver/Intestine Committees
- April 2017 – Committee considers this feedback during the in-person meeting and whether proposal is ready for public comment in July 2017.
- October 2017 – Committee considers public comments on the proposal and whether proposal is ready for the OPTN/UNOS Board of Directors in December 2017.

Next steps:

- UNOS staff will report back to the Committee on the status of the language pertaining patient transfer.
- The Chair and Vice Chair will present to key stakeholder committees in March 2017.

2. Public Comment Proposal - Improving Allocation of En-Bloc Kidneys

The Committee heard a presentation from the OPTN/UNOS Kidney Transplantation Committee about improving the use of en-bloc kidneys.

Summary of discussion:

The Vice Chair of the Kidney Transplantation Committee shared a presentation on the proposal to improve the allocation if en-bloc kidneys. In order to address the supply-demand disparity noted in kidney transplantation, often kidneys from small deceased pediatric organ donors are utilized in en-bloc transplants. This practice also helps mitigate the technical challenges and potential for complications associated with the procedure. However, centers may be reluctant to

transplant single kidneys from small donors due to technical challenges, inferior function, and poor outcomes. The Kidney Committee noted several challenges to en-bloc kidney allocation:

- No OPTN policy on allocating en-bloc kidneys
- DonorNet® overestimates KDPI score for en bloc kidneys, potentially screening medically suitable candidates off the match run
- DonorNet® has communication limitations

The Kidney Committee's Vice Chair then profiled how the proposed policy resolves the problems outlined above. The five key tenets of the proposal include:

- Base allocation of en-bloc kidneys on donor weight
- Allocate en-bloc kidneys according to Sequence A
- Mask KDPI score in en bloc kidney allocation
- Centers must indicate to the OPTN Contractor that they accept and transplant en bloc kidneys in order to receive en bloc offers
- Surgeons can still split en bloc kidneys if they determine they can be transplanted singly

The proposed solution is to establish a weight threshold for mandatory en-bloc sharing:

- Less than 15 kg = MUST offer as en-bloc
- At least 15 kg and less than 25 kg = OPTION to offer en-bloc or individually

The basis for the weight thresholds in the proposal were based on number of kidneys transplanted en-bloc from deceased pediatric donors during the period 2010 to 2015. The vast majority of kidneys from donors less than or equal to 12 kg were transplanted en-bloc. Kidney transplants from donors 13-16 kg we performed en-bloc about half the time. En-bloc kidney transplants were very rare for pediatric donors greater than 25 kg.

At the conclusion of the presentation, the Kidney Committee representative asked for feedback on the following; should the weight threshold be increased for mandatory en-bloc kidney allocation and remove option to allocate kidneys from donors 15 to 25 kg?

The Chair thanked the representative from the Kidney Committee for the presentation and opened the floor for discussion. Several members of the Pediatric Committee inquired about the availability of data on outcomes for kidneys from the "intermediate" weight range (12-25 kg donors). The presenter responded that there is no specific outcome data available from the OPTN. A literature review was conducted for outcome data and the outcomes were very good. The intent of the policy is to meet everyone's needs without disadvantaging any groups.

Another member asked a related question, for those kidneys that were allocated en-bloc, did the Kidney Committee have any data on the number that were later split, or are the majority still being transplanted en-bloc? The presenter responded that there is no good data to describe the frequency of this practice. The sense of the Kidney Committee was that it is not common for kidneys allocated en-bloc to be later split and transplanted as single kidneys. There are regional differences in clinical practices and the Committee wanted to preserve the ability for a program to do this.

One member of the Pediatric Committee asked, what was the input from the OPO community on this proposal? Several OPO representatives participated in the Kidney working group discussions. These representatives were very comfortable how the policy was developed. The sentiment was that a policy on en-bloc allocation was needed to give the OPO community guidance on this issue.

Another member of the Pediatric Community commented that many kidneys from donors less than 25 kg are not usable in pediatric candidates. Transplant programs don't like to use kidneys

with small anatomy in small recipients due to the potential for vascular complications. They asked, was there data available about discard rates based on the inability to allocate en-bloc kidneys? The representative from the Kidney Committee commented that she was not aware of good data on this topic.

The Kidney Committee representative then asked the Pediatric Committee specifically about support for modifying the weight range in the proposal:

- Increase the upper limit of mandatory weight range to 20 kg
- Removal of the "intermediate" weight range (15-25 kg) to allow OPOs the choice to allocate either as en-bloc or single kidney

Members of the Committee felt this modification was appropriate. One member felt kidneys from donors 20-25 kg are easily split into two transplantable kidneys, and including an upper limit of 25 kg was too high.

At the conclusion of the discussion, the Chair asked for a vote on the Kidney Committee's proposal with the changes to:

- Agree with the premise that donor weight drive en-bloc kidney allocation
- Increase the upper limit of mandatory weight range to 20 kg
- Removal of the "intermediate" weight range (15-25 kg) to allow OPOs the choice to allocate either as en-bloc or single kidney

The Pediatric Committee approved the proposal as amended (Yes – 10, No – 0, Abstain – 0).

Next steps:

- UNOS staff will draft a response on behalf of the Committee and share with leadership. Once reviewed, the response will be posted on the OPTN website.

3. Request for Feedback - Remove Disincentives for Living Donation

The Living Donor Committee is seeking pre-public comment feedback on a plan to add a companion resource to the UNOS educational brochure, "Living Donation: Information you need to know."

Summary of discussion:

In the last several months, the Committee has discussed the idea of promoting living donation. After guidance from UNOS staff, the Committee understands that it is outside the scope of the OPTN to directly *promote* living donation. The Chair acknowledged this position and indicated that advocacy outside the OPTN is possible with other organizations. He encouraged Committee members to support these efforts if this was an area of interest.

UNOS staff shared the historical perspective it is within the scope of the OPTN (and committees) to pursue projects that remove disincentives for living donation. The OPTN/UNOS Living Donor Committee has been working on such a project and asked for pre-public comment feedback from the Pediatric Committee. The Living Donor Committee's project to *Remove Disincentives for Candidates to Consider Living Donation* is intended to:

- Summarize the potential benefits and risks of living donor transplantation as a treatment option.
- Provide a series of strategies for overcoming common barriers to pursuit of living donor transplantation, such as approaches to countering fears based on misinformation and techniques for sharing the need for an organ donor with a support network.

Committee members were sent materials on this proposal with the meeting materials two weeks prior to the call. This included:

- Memo from the OPTN/UNOS Living Donor Committee Chair
- Draft brochure
- Feedback from other reviewers

At the conclusion of this overview, the Chair asked for volunteers to review the materials from the Living Donor Committee and provide feedback. Five Committee members agreed to serve as reviewers for this resource. UNOS staff asked that feedback be shared by the beginning of March 2017.

Next steps:

- Reviewers to share their feedback on the brochure *Living Donation: Information you need to know* with UNOS staff and Committee leadership by the beginning of March 2017. Thereafter, the response will be shared with the Living Donor Committee.

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

Upcoming Meetings

- 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)

Attendance

- **Committee Members**
  - William Mahle, M.D., Chair
  - George Mazariegos, M.D., Vice Chair
  - Stephen Gray, M.D., Region 3
  - Gregory Abrahamian, M.D., Region 4
  - Kristin Mekeel, M.D., Region 5
  - Evelyn Hsu, M.D., Region 6
  - Margaret Knight, at-large
  - Melissa McQueen, at-large
  - Thomas Nakagawa, M.D., at-large
  - Eileen Brewer, M.D., at-large
- **HRSA Representatives**
  - Monica Lin
- **SRTR Staff**
  - Jodi Smith, M.D.
- **OPTN/UNOS Staff**
  - Christopher L. Wholley, M.S.A.
  - Kimberly Uccellini
  - Amanda Robinson
  - Chelsea Hayes
- **Other Attendees**
  - Nicole Turgeon, M.D., Kidney Transplantation Committee