

**OPTN/UNOS Pediatric Transplantation Committee
Report to the Board of Directors
November 12-13, 2012
St. Louis, Missouri**

Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items

- The Committee continues to discuss adding pediatric transplantation experience considerations in the bylaws. (Item 1, Page 2)
- The Committee discussed OPTN Final Rule requirements for organ allocation policy development. (Item 2, Page 5)
 - Kidney Allocation Policy Review (Item 2a, Page 5)
 - Thoracic Organ Allocation Policy Review (Item 2b, Page 6)
- The Committee discussed the OPTN Policy Rewrite Proposal distributed for public comment. (Item 3, Page 8)

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**Heung Bae Kim, M.D., Chair
Eileen Brewer, M.D., Vice Chair**

The following report presents the OPTN/UNOS Pediatric Transplantation Committee's deliberations and recommendations on matters considered during its June 19, 2012, teleconference with members of the Thoracic Organ Transplantation Committee, and its September 6, 2012, meeting.

1. Addition of Pediatric Transplantation Experience Considerations in the Bylaws

At its September 6, 2012, meeting, UNOS staff began this discussion by reviewing the OPTN Strategic Plan, focusing on a key initiative in Goal 4, Objective B, which states, "Develop separate program requirements for pediatric programs." UNOS staff continued with an explanation of the problem encountered by the Membership and Professional Standards Committee (MPSC), and that the Committee has been asked to help address. To summarize: transplant programs that predominately care for pediatric patients ("pediatric programs") will occasionally submit for approval a key personnel applicant who meets or exceeds the criteria for an established pathway, as defined in the OPTN Bylaws; however, the proposed key personnel applicant has no pediatric transplantation experience. These applications have historically been approved though MPSC members have reservations about doing so due to the key personnel applicant's lack of pediatric transplant experience. When reviewing such applications, the MPSC feels obligated to approve these key personnel because they meet the explicit requirements of the bylaws, and because there are no other bylaw provisions that address or allow the MPSC discretion in these situations.

The Committee has spent significant amounts of time trying to determine organ-specific, pediatric transplant case volume requirements from one's medical training, subsequent practice experience, or a combination of the two, which could serve as minimal criteria that would be expected of key personnel at "pediatric programs." Due in part to the relatively small volume of pediatric transplants as compared to the number of adult transplants, the Committee has struggled to establish reasonable and meaningful minimum criteria that are also supported with data-driven evidence. Without this data-driven evidence, the Committee has had difficulty getting the larger transplant community to support these detailed requirements.

UNOS staff suggested for the Committee's consideration another approach to address this problem. Instead of establishing detailed criteria to qualify key personnel at programs that primarily transplant pediatric patients, the bylaws could be modified to include language that disqualifies key personnel applicants who do not have pediatric transplant experience. For example, each organ-specific appendix to the bylaws that outlines the key personnel pathways could include additional language that states something to the effect of:

If the primary transplant physician at a pediatric [ORGAN] program has completed the 12-month transplant [ORGAN] fellowship pathway, the clinical experience pathway, or is seeking conditional approval, then at least half of the cases that contribute towards the volume requirements in these pathways must include patients under the age of 18.

The suggested expectation that half of the cases cited in a key personnel application are with pediatric patients is rooted in the Centers for Medicare & Medicaid Services' (CMS)

Conditions of Participation (CoP). The CMS CoP indicates that a transplant program that performs 50 percent or more of its transplants (in a 12-month period) in a particular age group (adult versus pediatric) is not required to apply, and be separately approved, for program designation for the minority age group. This essentially defines a pediatric transplant program as one that transplants pediatric patients 50 percent of the time or more over a 12-month period.

Committee members indicated that this requirement would likely be difficult for newly-trained doctors and those whose career experience is mainly at adult hospitals. This is not necessarily a negative consequence, but this is a point of concern that will probably be noted by the community. UNOS staff replied that this is true regarding the different, detailed pathways in the bylaws, and to some extent that is the intent behind these changes. Although these conditions may be difficult for some to qualify, it is important to understand that this will not prevent appropriate personnel from serving in these key personnel roles at "pediatric programs." The current, organ-specific "pediatric pathways" for key personnel applicants at programs that primarily transplant pediatric patients would remain so that these key personnel applicants could be approved by the MPSC if they are qualified. (Each organ-specific "pediatric pathway" requires, among other things, that the candidate participate in an informal discussion with the MPSC, or an Ad Hoc Subcommittee of the MPSC, for it to make a determination on their application.)

This strategy offered for consideration fails to put safety assurances in place for those pediatric transplant candidates who are registered at large transplant programs that primarily do adult transplants. Several of the largest pediatric transplant facilities in the country are at transplant hospitals that primarily transplant adults. It is understood that this proposal does not address these hospitals, and this is not ideal, but there doesn't seem to be any way around this at the moment. UNOS staff responded that expanding the scope of the project to include those programs would entail a dramatic shift in what the bylaws demand. That is not to say that such a shift couldn't be pursued, but whether the larger transplant community would support that shift must be considered, especially as it has not been supportive of changes in the past that pertain to this topic.

Committee members also expressed concern that the suggested bylaw changes did not address the skills that are unique to transplanting the youngest pediatric patients. Without this additional detail, there is concern that a key personnel applicant may meet this proposed bylaw requirement exclusively by transplanting teenagers. Although this concern was expressed in past Committee conversations, more detailed, age group specific requirements were not included because that would reintroduce specific case volume requirements that have proven difficult to establish and support. Additionally, there is an assumption that a transplant surgeon or physician who meets the suggested 50 percent pediatric transplants requirement will have experience treating pediatric transplant patients with varying conditions and across the range of pediatric ages.

The Chair acknowledged two options: define a pediatric transplant program, and subsequently the criteria to serve in a key personnel role at that program; or, define what constitutes a pediatric transplant (as the Committee is more concerned about the judgment and skill to care for infants and young children, not necessarily older teenagers) and subsequently, the qualifying criteria expected of individuals performing those pediatric transplants. These efforts do not have to be independent of one another. Based on the lack of success in the past, there are concerns that solely pursuing the Committee's ideal solution will result in the status quo and the corresponding problems remaining indefinitely. A Committee member commented that the age-specific criteria would be an incremental gain relative to what has been proposed and it didn't seem prudent to sacrifice potential progress for this incremental gain.

The Committee proceeded to discuss evidence necessary to support its recommendations. The key personnel criteria were arbitrarily determined upon their introduction in the bylaws, and it seems somewhat unreasonable to have a higher standard for addressing these bylaws' silence on pediatric transplantation. To satisfy demands for data that support possible criteria that would require involvement with a minimum number of pediatric transplant cases, the Committee discussed a possible solution that is derived from the bylaws' current key personnel case volume requirements. This solution requires analyzing and determining the mean number of transplants that occur at an "average" transplant program. The key personnel case volume requirements that are in the bylaws for each respective organ could then be compared to this determined mean number of transplants at the "average adult transplant program" to establish the general percentage of cases that is expected of one that is qualified to serve as transplant center's primary surgeon or primary physician. To determine the case volume requirements for those centers that primarily transplant pediatric patients, this same percentage could then be applied to an analysis that establishes the number of transplants performed at the "average pediatric transplant program." This would produce a number of pediatric transplant cases that would be expected of key personnel at a "pediatric" transplant program that is comparable to the current bylaw requirements. A similar approach avoids determining what constitutes an "average program," and compares the number of cases required of key personnel in the bylaws to the total number of transplants performed over the same time period. This would also produce an evidence-based factor that could then be applied to the total number of pediatric transplants that are performed over the same time frame. Due in part to the low volume thresholds that this general approach would produce, this solution is not something that Committee members necessarily support, but it is another possible solution. Alternatively, the Committee could expand upon the number of required cases determined by these analyses and argue that the percentage of cases in the current bylaws applied to pediatric transplants sets a minimal bar, and the Committee believes this bar should be raised.

The Chair stated another reason he supports the newly proposed approach is his anticipation that transplant hospitals' behavior regarding where pediatric patients are treated will eventually change if the OPTN makes a pediatric transplant program distinction. Over time, he envisions the public, payers, and transplant hospitals questioning why a child is being treated at a transplant hospital without a CMS or OPTN pediatric designation. An OPTN definition for a pediatric transplant program is critical to this change. In response, the Vice Chair mentioned large transplant programs whose volume of pediatric transplants is equivalent to large, independent pediatric transplant hospitals. She said she has also struggled with how to assure the framework for good care existed for pediatric patients being treated at those hospitals. Acknowledging those struggles, she indicated hope that a natural resistance to programs operating outside of an established framework for pediatric programs would develop. Slightly changing the environment could have a significant impact on how the transplant community thinks about pediatric transplantation. To encourage this shift, a Committee member suggested providing an option to qualify for programs that otherwise would not be required to qualify as a pediatric program.

The immediate past Chair of the Committee, David Campbell, M.D., commented that he has also worked on similar efforts with the Committee. Agreeing with the need for bylaw considerations that specifically address experience with the youngest transplant patients, and at every transplant hospital, he stated that the Committee must make some progress on this matter and small steps seem most likely to gain traction. In response, a Committee member observed that there seemed to be agreement that it should recommend establishing a pediatric transplant program definition that is modeled after what is used by CMS- a pediatric transplant program is one that does 50 percent or more of its transplants

over the last 12-month period in patients younger than 18 years of age. A vote was taken to establish the Committee's support for this definition and the Committee unanimously voted in favor (19 support, 0 oppose, 0 abstentions).

The next steps include outlining the problem and potential solutions in a concept document to solicit feedback from the organ-specific committees as well as the American Society of Transplant Surgeons (ASTS) and the International Society for Heart & Lung Transplantation (ISHLT). This document would focus on the problem of key personnel roles being filled by applicants with no pediatric transplant experience at transplant centers that primarily transplant pediatric patients, potential solutions to address this issue, and the Committee's support for a definition of a pediatric program that aligns with the CMS definition. The potential solutions will include the 50 percent consideration discussed during this meeting, as well as the case volume requirements option which will include, as an example, the case volumes proposed by the Kidney and Thoracic Working Groups, respectively. Incorporating these groups' feedback and obtaining their support will increase the likelihood of any success. The Committee agreed with this approach.

2. Discussion of OPTN Final Rule Requirements for Organ Allocation Policy Development

2a. Kidney Allocation Policy Review

To provide greater detail and familiarity for new Committee members, the Vice Chair reviewed the desired approach to improve access to transplant for highly sensitized pediatric kidney candidates through regional sharing of deceased donor kidneys. This concept was developed by the Kidney Working Group and is based on conversations with members of the Kidney Transplantation and Histocompatibility Committees.

A Committee member asked if it should be clarified that this concept could also apply to donors younger than 35 years of age, considering the new kidney allocation system's use of a kidney donor profile index (KDPI) and the possibility of this concept being approved before a new kidney allocation system is implemented. UNOS Staff responded that formal consideration of this concept is anticipated to follow the formal consideration of the new kidney allocation proposal. As new kidney allocation policy has yet to be adopted, and considering the lengthy policy development process, the Committee thought it would be prudent to clarify this point. Specifically, it intends for this concept to be applied to those kidney donors whom pediatric candidates are granted priority, regardless if that priority is determined by donor age or KDPI.

After reviewing the concept, the Committee discussed the next steps it needs to execute. As the concept includes some OPO involvement, and because the members of the OPO community have not been involved in the previous discussions, the Committee would like to discuss this concept with representatives of the OPO Committee. This discussion would focus on the logistics involved with this concept, specifically listing additional antigens and the shipment (and possible reshipment) of these kidneys.

Additionally, it also needs to be determined who will review the positive crossmatch reports that are alluded to in the concept brief. Committee members commented that the Histocompatibility Committee seemed best suited to undertake these reviews because of their expertise and because it already has a process in place for reviewing positive crossmatch reports. The Committee recommends that the Histocompatibility Committee review these positive crossmatch reports with the condition that the Committee reviews all positive crossmatch reports and the subsequent recommendations made by the reviewers so that it may consider this information in its evaluation of this concept.

Committee members asked how this concept would be implemented if it is ultimately adopted by the Board of Directors. Recognizing that this concept is somewhat hinged to the new kidney allocation system, and that the concept has been discussed as a trial system, it appears that this concept should be proposed as a variance. Specifically, a committee-sponsored alternative allocation system that is open to those members that wish join it.

Another Committee member asked if the CPRA used to qualify candidates would be a current CPRA or historical values. Centers often work with candidates to reduce their CPRA, and these candidates may have fluctuating CPRAs that would qualify one week, but not the next. How will this concept address pediatric candidates in a similar situation? Although the Kidney Working Group has not discussed this situation in depth, the constructs of the system would seem to dictate that current CPRAs are used for the purposes of determining a candidate's eligibility.

2b. Thoracic Organ Allocation Policy Review

Pediatric Heart Allocation Changes Proposal- During the joint Pediatric/Thoracic Committee teleconference in July, as well as during the Committee's September 2012 meeting, the Committee reviewed the concepts to change pediatric heart allocation that are intended to be distributed for public comment in spring 2013. These concepts have been developed in a joint effort between the Committee's Thoracic Working Group and the Heart Subcommittee of the Thoracic Organ Transplantation Committee (the Thoracic Committee). UNOS staff is working with the Chair of the Thoracic Committee to finalize the final policy language to be recommended with this proposal. The proposal has four major components:

- Modify pediatric Status 1A and 1B criteria;
- Increase the eligible isohemagglutinin titer from 1:4 to 1:16, for candidates one year of age and older to qualify for an blood group incompatible heart transplant;
- Increase allocation priority for potential transplant recipients eligible for blood group incompatible hearts and potential recipients younger than one; and,
- Eliminate the *in utero* listing option.

The Committee raised some concerns that these pediatric heart Status 1A and Status 1B criteria changes will preferentially weigh the system towards pediatric heart candidates with congenital heart defects. Primarily, the concern is that candidates with cardiomyopathy (who the data show do relatively well after a transplant) would never be able to be listed as Status 1A, and these patients outcomes may suffer accordingly. Such a policy change may dictate pediatric patients with cardiomyopathy to more commonly have ventricular assist devices (VADs) implanted while waiting for a heart transplant.

In response, the Committee's crossover representative to the Thoracic Committee, Bill Mahle, MD, indicated that the community is getting better with VADs for pediatric patients with cardiomyopathy, but this is not a great option for deteriorating congenital heart transplant candidates. Earlier discussions regarding this topic indicated that pediatric patients with cardiomyopathy could be supported safely and successfully with VADs while waiting for an appropriate heart offer. Because congenital heart patients with VADs have not proven to be as successful, and as there are not other effective methods to support congenital heart candidates without a transplant, they should have an increased priority. Committee members supported this, but expressed additional concern

for those cardiomyopathy patients older than one year of age who are not as successfully treated with VADs. Understanding these concerns, the Committee's Thoracic Committee crossover representative stated that no data were reviewed which showed that these older than one year of age cardiomyopathy patients face significantly higher waiting list mortality. Thus, the Working Group couldn't rationalize including this group explicitly in the pediatric heart Status 1A definition. The Committee was reminded that pediatric cardiomyopathy candidates that are of the utmost urgency are not completely excluded from being listed as pediatric Status 1A- transplant programs whose urgent candidates do not meet the criteria defined in policy can always request that a patient be listed as Status 1A by exception.

Another Committee member questioned the pediatric Status 1A exception language that associates this classification, and the corresponding process, as one for a candidate who has a life expectancy without a heart transplant of less than 14 days. As many of the candidates who will qualify under the proposed pediatric Status 1A criteria commonly live longer than 14 days, a Committee member suggested language similar to what is used in the Pediatric Status 1B policy, "if the candidate has an urgency and potential for benefit comparable to that of other Status 1B candidates." Other Committee members indicated that this 14-day requirement mimics the language for adult Status 1A heart candidates by exception as there is a desire for consistency (to the extent possible) between pediatric heart policy and corresponding adult heart policy. Nevertheless, Committee members thought this reference to 14-days is somewhat misleading and recommended that "urgency and potential for comparable benefit" be used instead.

Reviewing the potential policy changes pertaining to blood group-incompatible heart allocation, there was some confusion regarding the term "consent." UNOS staff said that this is related to UNetSM functionality that requires heart candidates to indicate explicitly that they are willing to accept a blood group-incompatible heart. From this perspective of how the system operates, considering plain language, and only wanting to change the maximum qualifying isohemagglutinin titer, the word consent was suggested and used for this draft. Committee members cautioned against using the word "consent" in this instance because of the varying interpretations of this word.

UNOS staff reiterated that it is working with the leadership of both Committees to finalize the policy language so a public comment proposal for these changes can be distributed in spring 2013. This feedback will be brought forward for consideration during those discussions. Acknowledging this, and recognizing no major disagreements with the concepts that were outlined and discussed, a motion was made for the Committee to support sending this proposal for public comment, upon the policy language being finalized. The Committee unanimously supported this motion, 17-support, 0-oppose, 0-abstentions.

Outcomes Review for Congenital Heart Patients: MPSC and Thoracic Committee Memorandum- At its March 2012 meeting, the Thoracic Committee discussed a question posed by the MPSC regarding how it's Performance Analysis and Improvement Subcommittee (PAIS) should evaluate candidates who are 18 years and older who are transplanted at transplant centers that primarily transplant pediatric patients. The Thoracic Committee responded as follows:

"The Thoracic Organ Transplantation Committee determined that an equitable solution is for the MPSC to associate, in general, outcomes of a transplant recipient with the transplant program that performed the transplant. The MPSC should evaluate an adult recipient of a heart transplant performed at a pediatric transplant

program as part of the overall number of transplants performed by that pediatric heart transplant program.”

The Thoracic Committee also asked that this response be shared with the Committee. A member of the Committee that also serves on the MPSC provided some background for these earlier discussions. The situation described in the memorandum is frequently seen with adult congenital heart patients who are commonly treated at transplant hospitals that primarily transplant pediatric patients.

No explicit feedback was requested of the Committee, and it did not have any comments it felt must be shared with the Thoracic Committee or MPSC. The Committee appreciated being informed of the discussions had and the decisions made.

Inactive Priority 1 Lung Candidates Accruing Waiting Time- The Committee reviewed the response from the Thoracic Committee regarding this memo. Additionally, UNOS staff informed the Committee that the apparent discrepancy between current programming and the policy is being corrected during the Chrysalis project. If the Committee is to pursue those recommendations from the Thoracic Committee, and what it also believes is ideal, then this would require a policy change and the entire process that it entails. UNOS staff reminded the Committee that modifying UNetSM as suggested is what the original policy stated when it was approved in June 2008. This is important to note because this aspect of policy was subsequently modified prior to implementation so that the programming effort was not as labor intensive, but still achieved the Committee’s goals. The Committee indicated that it did not believe the benefit gained by changing the policy (and implementing that change) would justify the necessary effort.

3. Policy Rewrite Review

UNOS staff provided background on the origin and purpose of the proposed plain language rewrite of OPTN policies. The Committee was reminded that the rewrite intends to retain the intent of current OPTN policy, but to communicate that intent more plainly and clearly. Committee members reviewed the policy rewrite document prior to meeting, focusing on those policies that addressed some aspect of pediatric transplantation. These individual reviews produced questions and comments that were discussed by the full Committee. Discussion yielded a number of edits and recommendations for UNOS staff to consider.

**OPTN/UNOS Pediatric Transplantation Meeting
June 19, 2012**

Teleconference with the Thoracic Organ Transplantation Committee

NAME	COMMITTEE POSITION	Phone
David Campbell, MD	Chair	
Heung Bae Kim, MD	Vice Chair	
Laura O'Melia, CPNP	Regional Representative	
Stephen Dunn, MD	Regional Representative	
Alfonso Campos, MD	Regional Representative	
Jose Almeda, MD	Regional Representative	
Debra Strichartz, RN, BA, CCTC	Regional Representative	
Andre Dick, MD, FACS	Regional Representative	
Sharon Bartosh, MD	Regional Representative	X
Jeffrey Lowell, MD	Regional Representative	
Kishore Iyer, MD	Regional Representative	
Jeff Shuhaiber, MD	Regional Representative	
Kathy Jabs, MD	Regional Representative	
Sandra Amaral, MD	At Large	X
Eileen Brewer, MD	At Large	X
John Bucuvalas, MD	At Large	
Blanche Chavers, MD	At Large	
Shylah Haldeman, RN	At Large	
Clifford Chin, MD	At Large	X
Carmen Cosio, MD	At Large	
Alan Farney, MD, PhD	At Large	
Simon Horslen, MB, ChB	At Large	
Kimberly Hoagwood, PhD	At Large	
William Mahle, MD	At Large	X
Debbi McRann, RN	At Large	
Douglas Milbrath	At Large	
Gary Visner, DO	At Large	
Jerry Wright, RN, CPTC	At Large	
James Bowman, MD	HRSA	X
Ba Lin, MS, MPH	HRSA	X
Jodi Smith, MD	SRTR- MMRF	X
Wida Cherikh, PhD	UNOS Research	X
Chad Waller, MS	Committee Liaison	X
Jory Parker	UNOS Business Analyst	X

OPTN/UNOS Pediatric Transplantation Meeting

September 6, 2012

Chicago, Illinois

NAME	COMMITTEE POSITION	In Person
Heung Bae Kim, MD	Chair	X
Eileen Brewer, MD	Vice Chair	X
David Campbell, MD	Ex-Officio	Phone
Laura O'Melia, CPNP	Regional Representative	X
Stephen Dunn, MD	Regional Representative	X
Jennifer Garcia, MD	Regional Representative	X
Jose Almeda, MD	Regional Representative	X
David Rosenthal, MD	Regional Representative	X
Andre Dick, MD, FACS	Regional Representative	X
Sharon Bartosh, MD	Regional Representative	X
Richard Hendrickson, MD	Regional Representative	
Linda Addonizio, MD	Regional Representative	Phone
Gregory Tiao, MD	Regional Representative	X
Bret Mettler, MD	Regional Representative	X
Sandra Amaral, MD	At Large	X
John Bucuvalas, MD	At Large	
Blanche Chavers, MD	At Large	
Clifford Chin, MD	At Large	X
Carmen Cosio, MD	At Large	X
Alan Farney, MD, PhD	At Large	X
Kimberly Hoagwood, PhD	At Large	X
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William Mahle, MD	At Large	Phone
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Douglas Milbrath	At Large	X
Gary Visner, DO	At Large	X
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Jodi Smith, MD	SRTR- MMRF	X
Susan Leppke, MPH	SRTR-MMRF	Phone
Wida Cherikh, PhD	UNOS Research Liaison	X
Chad Waller, MS	UNOS Committee Liaison	X
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