OPTN/UNOS Pediatric Transplantation Committee
Interim Report: September 6, 2012 Meeting
Chicago, Illinois

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The following report presents the OPTN/UNOS Pediatric Transplantation Committee's deliberations and recommendations on matters considered during its September 6, 2012, meeting.

1. Introduction and Board of Directors Meeting Update

The Pediatric Transplantation Committee (the Committee) was welcomed by the Chair and members subsequently introduced themselves. To acquaint new members of the Committee, and as a refresher for the remainder, OPTN/UNOS research liaison for the Committee, Wida Cherikh, Ph.D., explained the process for committee data requests to support the Committee's pursuit of evidence based policy development. Following this presentation, the Committee's liaison for the Scientific Registry of Transplant Recipients (SRTR), Jodi Smith, M.D., oriented the Committee on the SRTR's function and its role in inferential data analyses requested by the Committee.

The UNOS Committee liaison, Chad Waller, provided a brief update of the June 2012 OPTN/UNOS Board of Directors meeting. The Committee reviewed the respective OPTN and UNOS Strategic plans, and the Committee liaison directed the Committee towards online versions of the Executive Summary and Policy Notice that UNOS produced following this meeting.

2. 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.

Prior to its September 6th meeting, Committee members reviewed the rewrite proposal with particular focus on pediatric policies that were highlighted by UNOS staff. This highlighted list of policies was further divided by organ, and each of the Committee's organ specific working groups were assigned policies relating to their areas of expertise. Using the highlighted list of pediatric policies as a guide, the Committee went through the entire body of rewritten policy language, stopping for discussion at those policies where comments and questions were raised by members. The following summarizes that feedback and any subsequent committee discussion:

- *5.1(D) Heart Acceptance Criteria*- The Committee asked if it is clear to the intended audience what is meant by the term "minimal acceptance criteria," and if the word "minimal" is necessary. The Committee suggested that the term "acceptance criteria" would yield additional simplicity without the loss of meaning. Whichever term is best, the Committee suggested adding it to the definitions section.

- *6.3 Allocation of Liver-Intestine from Donors Aged 0 to 10 Years*- Committee members noted how the allocation classifications reference pediatric patients by an age range and

distinguish potential transplant recipients that are 18 and older with the term "adult." Referencing classification #3 in Table 6-1, the Committee thought that using the age range as written to define the included patient population has the potential to be misinterpreted. That is, some might interpret "12 to 17 years of age" as including anyone that is 12 years of age but has yet to turn 18 years of age, while others may interpret it as anyone that is 12 years of age but has yet to turn 17 years of age. To avoid this confusion, the Committee recommends using 'younger than' or 'older than' along with one of the ages where the range is divided to specifically define each respective age range. For example- 18 years of age and older, less than 18 years of age; younger than 12 years of age, 12 to younger than 18 years of age, 18 years of age and older; etc. The Committee recommends using this general convention for every policy that distinguishes adult and pediatric candidates, as well as those policies that subdivide pediatric candidates into other age ranges. This could include a general definition that adults are defined as, "18 years of age and older at the time of registration," since this is true across all organ groups.

- *6.4 Allocation of Liver-Intestine from Donors Aged at Least 11 Years*- The policy title references donors that are "at least 11 years," and the first sentence of the policy references donors that are, "older than 10-years." The Committee noted that policy 6.4 is a good illustration of the discussion it just had, the potential for confusion, and that consistency will provide clarity.

- *7.1(F) Pediatric Heart Status 2*- The Committee noted that the language used to define pediatric candidates, that is "If the candidate registers on the waiting list before turning 18 years old," was a good example of its preference for distinguishing age groups, as expressed during its discussion of policy 6.3.

- *9.3 Points*- Committee members commented that this table is helpful for understanding the complexities of kidney allocation. As the table references allocation sequences that are detailed later in the policy, the Committee recommended labeling the sequences in the second column of Table 9-1 as 9.6(A), 9.6(B), etc., to give the reader additional guidance towards these allocation sequences that are located in a section of policy that is after this table. This may also be helpful because only section 9.6(D) uses the word "sequence," but even it doesn't use the term "allocation sequence" as referenced in the column header.

  The Committee also pointed out that Table 9-1 does not reflect its preference for defining age ranges. Instead, the Committee would prefer "less than 11 years old at the time of…" and "11 through younger than 18 years old at the time of..."

  A Committee member commented that the table could be simplified by removing the five rows that include pediatric age ranges, and display that information with a matrix. Because of the duplication in some of the cells, this additional matrix could be simplified while also providing a linear way of presenting all the relevant information for one particular age group.

- *9.4 Waiting Time*- Nephrologists on the Committee questioned if listing the three dialysis locations was necessary detail for the second criterion. The Committee suggested that it would be sufficient for the policy to read: "The candidate began dialysis that is regularly administered for end stage renal disease."

- *10.1(C) Pediatric Status 1B*- Committee members commented that Status 1B criterion (v) from the current policy represents candidates with chronic liver disease. As written in the policy rewrite proposal, including hepatoblastoma candidates in this list of criteria is problematic because the rewritten requirement in 10.1(C), 2, says that candidates must have "a MELD/PELD greater than 25;" however, there is no MELD/PELD requirement in current policy for Status 1B hepatoblastoma candidates. A suggestion is:

  10.1(C) Pediatric Status 1B
  A candidate may be classified as Pediatric Status 1B if the candidate registers on the waiting list before turning 18 years of age and meets one of the following requirements:
  1) Has a biopsy proven hepatoblastoma without evidence of metastatic disease; or,
  2) Has a MELD/PELD greater than 25 and has at least one of the following conditions:
     i. Is on a mechanical ventilator
     ii. Has gastrointestinal bleeding requiring more than 30 cc/kg of red blood cell replacement within the previous 24 hours
     iii. Is a liver-intestine candidate and has gastrointestinal bleeding requiring more than 10 cc/kg of red blood cell replacement within the previous 24 hours
     iv. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemodilution (CVVH), or continuous veno-venous hemodialysis (CVVD)
     v. Has a Glasgow Coma Score (GCS) less than 10 within 48 hours of the Status 1B registration or extension
     vi. Has a biopsy proven hepatoblastoma without evidence of metastatic disease.

  Specifically looking at the terminology used in (iv) above, Committee members stated that Continuous Renal Replacement Therapy (CRRT) is more commonly used in the literature and field than CVVH or CVVD. Committee members indicated that using CRRT here instead would be not be a substantive change because CRRT includes CVVH or CVVD. If this recommendation is acted on, it should also be addressed in other parts of the policy (e.g. Policy 10.1(A)).

- *10.2(B) MELD/PELD Exception Applications*- A Committee member pointed out the word "telephonic" and questioned if that was plain language.

  Additionally, Committee members did not think that the content in the second and third paragraphs of this section were clear. The Committee thought this confusion could be addressed by keeping the time limit considerations and the approve/decline options and consequences separate, and outlining the possible scenarios in chronological order. As such, the Committee suggests something to the effect of:

"Each RRB must review applications within 21 days of receiving the application. If the RRB does not review the application within 21 days of receiving the application, the candidate's transplant physician may register the candidate at the requested higher MELD/PELD score. However, the Liver and Intestinal Organ Transplantation Committee will retrospectively review these registrations and may refer these matters to the Membership and Professional Standards Committee for appropriate action according to Appendix L of the OPTN/UNOS Bylaws.

If the RRB does not approve the application, the candidate's transplant physician may appeal the decision and the RRB must meet with the physician by telephone or other electronic communication means to review the case. The candidate's transplant physician may register the candidate at the requested higher MELD/PELD score; however, the Liver and Intestinal Organ Transplantation Committee will retrospectively review these registrations and may refer these matters to the Membership and Professional Standards Committee for appropriate action according to Appendix L of the OPTN/UNOS Bylaws."

- *10.2(D) Specific MELD/PELD Exceptions*- First, the Committee pointed out that the age distinctions in Table 10-1 did not align with its earlier recommendation. This table should be included in referencing adults as 18 years of age and older, and pediatric as younger than 18 years of age.

  Additionally, the Committee stated that, "a 10 percentage point increase in the candidate mortality equivalent every three months," should be reworded to say, "a 10 percentage point increase in the candidate's three month mortality risk."

- *10.5(C) Segmental Transplants*- The Committee noted that the policy as written indicates that Transplant Programs allocate organs; however, organ allocation, including segmental organ allocation, is performed by Organ Procurement Organizations (OPOs) not Transplant Programs.

  Additionally, the policy says, "Donors whose livers have the potential to be split must meet *all* of the following criteria." This is not accurate, and considerably more restrictive than current policy. In the current policy, these criteria designate donors that "would be *identified* on every OPO match run as potential splittable donors [*emphasis added*]." This distinction is important, and this policy is problematic as written, because recent Committee data analyses indicated that the majority of livers that are allocated as segments are from donors that do not meet all these criteria. As a recommendation, the sentence that follows the list of criteria should instead be brought forward to read:

  > The match run will identify donors whose livers can be split and regional recipients willing to accept a segmental graft if the donor meets all of the following criteria:
  >
  > 1. Less than 40 years of age
  > 2. On a single vasopressor or less
  > 3. Transaminases no greater than three times the normal level
  > 4. Body mass index (BMI) of 28 or less.

- *10.5(E) Blood Type and Liver Allocation*- The Committee believes that the third bullet is problematic. Because of the qualifier, "with a MELD or PELD score greater than or equal to 30," the Committee had some confusion, indicating that the third bullet might be interpreted to exclude blood type "O" Status 1A and Status 1B candidates. Additionally, this policy does not accommodate the second sentence of current policy 3.6.2.1, which says, "Any remaining blood type compatible candidates will appear on the match run list for blood type O donors after the blood type O and B candidate list has been exhausted at the regional and national level."

- *11.4(A) Sorting Within Each Classification*- In the second list, 3 and 4 reference components of the Lung Allocation Score (LAS). As this sorting order is for, "Lung candidates less than 12 years of age," who do not receive an LAS, the Committee noted that it did not seem correct for 3 and 4 to be included.

  Discussion around this issue led to another point regarding the order in which pediatric and adult information is communicated. Throughout the document there are sections that are further divided into policies that apply to pediatric candidates and those that apply to adult candidates. Sometimes the pediatric policies are presented first, sometimes the adult policies. To assist readers' navigation through the policies, it may be helpful to determine a specific order (oldest to youngest or youngest to oldest) to present these age specific policies, and use that order in every section where age distinctions are made.

- *11.5(B) Donors Aged 12 to 17 Years of Age*- In Table 11-8, Classifications 3-6 reference "Status 1" and "Status 2." As these classifications reference lung candidates younger than the age of 12, "Status 1" and "Status 2" should be replaced with "Priority 1" and "Priority 2," respectively.

- The Committee also noted a number of apparent typos.

3. Addition of Pediatric Transplantation Experience Considerations in the Bylaws

UNOS staff began the discussion by reviewing the OPTN Strategic Plan, focusing on a key initiative in Goal 4, Objective B that states, "Develop separate program requirements for pediatric programs." UNOS staff followed this with an explanation of the problem recognized 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 will occasionally submit a key personnel application that 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 their 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.

Prior to the Committee meeting, members received a summary of the efforts on this project which included recent Committee discussions, as well as historical accounts of past attempts to address this issue. This issue brief documented the outcomes of the current efforts and illustrated that the minimal progress and challenges faced when addressing this issue have proven to be a trend, and are not unique to the current composition of the Pediatric Committee. In the past, 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. These pediatric case volume requirements would be intended to serve as minimal criteria that would be expected of key personnel at any transplant program that primarily serves pediatric patients. Due in part to the small volume of pediatric transplants as compared to the number of adult transplants, it is difficult to establish reasonable and meaningful minimal 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.

One of the larger efforts towards addressing this general issue entailed surveying every transplant programs that had transplanted pediatric patients (the survey was originally distributed April 2002). The general purpose of this survey was to analyze those programs that were doing pediatric transplants (their facilities, personnel, outcomes, etc) to then determine some "average" characteristics that could be used to define a pediatric program and qualify key personnel at those programs. Ultimately, these efforts did not produce any changes to the bylaws. A Committee member who was a main contributor in developing this survey gave his account of that experience, the troubles faced then, and why those efforts were unsuccessful in producing change.

UNOS staff suggested for the Committee's consideration another strategy 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 that do not have pediatric transplant experience. For example, each organic-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. In addition to any criteria, any potential proposal must define what a "pediatric program" entails. Using a similar definition to what has already been established by CMS, and is used commonly in the field, appears to be the most logical recommendation.

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 contingency 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 programs that primarily transplant pediatric patients. The current, organ-specific "pediatric pathway" 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 appropriately qualified. (Each organ-specific "pediatric pathway" requires 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.)

New Committee members commented that 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. The Vice Chair commented that several of the largest pediatric transplant facilities in the country are within 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 smaller changes in the past that pertain to this topic.

The Chair reminded the Committee that this discussion regarding the scope of any proposal that addresses the bylaws lack of pediatric transplant training and experience for key personnel has been had numerous times recently. To avoid having that conversation again, the chair reiterated that the MPSC has been presented with key personnel applications for transplant programs at pediatric hospitals that meet the qualifications outlined in the bylaws, but have no pediatric transplant experience. The MPSC believes this is problematic, and as the current bylaws are silent on this issue, it has requested the Committee's assistance. If the Committee wants to address this issue, then he believes that focusing on solving the MPSC's problem will produce the most straightforward solution. This opinion was qualified with the fact that he has participated in numerous conversations about this subject, and originally believed that the Committee should pursue a solution that addressed pediatric transplants at every transplant hospital.

The Chair reminded the Committee that the OPTN does not officially categorize or qualify transplant programs as "pediatric" or "adult." After the final rule, CMS required transplant programs to be designated as "adult" or "pediatric," with the option of applying for both. The Chair recommended that a solution should be proposed that is consistent with the CMS CoP. First, the OPTN needs to define what qualifies as a pediatric transplant program. Once that definition is set, the next step is to determine what qualifications are requisite to serve in a key personnel role at that program.

Committee members 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 clearly 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 that 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. Finally, while the status quo indefinitely remains, there is nothing in the current bylaws that would prevent these key personnel applicants from being approved.

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 (recognizing the Committee is more concerned about the judgment, knowledge, and skill necessary to transplant infants and children, not necessarily older teenagers) and subsequently, the qualifying criteria expected of individuals performing those pediatric transplants.

A Committee member stated that it would be interesting to know the number of pediatric candidates that are transplanted at these centers that would deemed a pediatric transplant center by the definition above. Acknowledging the challenge and logistics, she indicated that she would prefer to set requirements for any hospital that wished to transplant pediatric candidates. Alluding to major metropolitan cities that have numerous centers that transplant pediatric patients, she argued that the pediatric patients in these major cities would be better served by one or two centers of excellence. A Committee member responded that this benefit could come at the cost of those candidates located in more sparse population areas, where there are less transplant programs. Preventing a 17-year old from being transplanted at a local hospital, where the nearest pediatric transplant program is over 500 miles away, would be a large, unnecessary burden on these pediatric patients and their families.

UNOS Staff reminded the Committee that these pursuits do not necessarily have to be independent of one another. If the Committee only pursues establishing pediatric transplant training and experience requirements for any transplant program that wishes to transplant pediatric patients, nothing will be any different in the interim. More importantly, 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.

The Committee proceeded to discuss evidence necessary to support any recommendations. Committee members commented that the key personnel criteria in the current bylaws were arbitrarily determined, and it seems somewhat unreasonable to have a higher standard for addressing the bylaws' silence on pediatric transplantation. A possible solution would be to compare the number of cases that are represented by the current key personnel requirements relative to the number of transplants that are performed at the average "adult" transplant center. This ratio could then be applied to the average "pediatric" transplant center to set the criteria expected of key personnel at these transplant centers. Due in part to the low volume thresholds that this 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 this ratio and argue that percentage of cases in the current bylaws applied to pediatric transplants sets a minimal bar, and the Committee believes this bar should be raised.

A member of the Committee's Kidney Working Group alluded to criteria that it had established for pediatric kidney surgeons in recent discussions, and whether those recommendations would be abandoned. UNOS staff reminded the Committee that although some tentative case volumes were agreed to (pediatric kidney surgeon, pediatric heart surgeon) a complete set of recommendations had not been developed. Those options are not off the table, but analyzing the progress thus far prompted a different strategy to be suggested for consideration.

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 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.

Alluding to Committee discussions surrounding the survey that it distributed in 2002, the Committee had similar aspirations then to make things better for pediatric transplant patients; however, the reality is no advances on this issue have been realized. As such, a Committee member that served during the development of that survey urged the Committee to seize this opportunity to make some progress, even if the solution is short of everything the Committee would desire. The Vice Chair echoed this point. The Committee responded that it supported making incremental progress, but the overall concern for pediatric patients at every transplant hospital should remain as a long term goal.

The Committee reviewed the current bylaw requirements for key personnel. The Committee again raised points of concern regarding the feasibility of key personnel applicants at pediatric programs meeting 50 percent of the current requirements. The Chair clarified that those transplant programs could also qualify key personnel using the "pediatric pathway" that is currently in the bylaws for each organ group, which this proposal does not intend to modify. The Committee raised additional concerns about experience with younger pediatric transplants patients. Although these concerns are valid, addressing this in a meaningful way will revert back to setting case volume requirements that have proven difficult to develop and build support among the community. 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 immediate past Chair of the Committee, David Campbell, M.D., commented that he has also worked on similar efforts with the Committee multiple times now. 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).

With this agreed to, the Chair directed the Committee's attention to the next steps that should be pursued. He proposed that the next steps would be to outline 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.

4. Status of 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 number of delays that have already been encountered during its 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 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.

5. Status of Thoracic Organ Allocation Policy Review

Pediatric Heart Allocation Changes

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 a 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.

Reviewing the changes to be proposed for pediatric heart candidates to qualify as Status 1A and Status 1B, Committee members questioned continuing to include patients treated with an intra-aortic balloon pump. It was questioned whether balloon pumps are used with enough

frequency to justify including it as its own criterion to qualify for pediatric Status 1A and why these patients couldn't qualify by citing the mechanical circulatory support criterion?

The Committee also raised concerns that these pediatric heart Status 1A and Status 1B criteria changes will cause a shift in the system that is preferential towards pediatric heart candidates with congenital heart defects. Primarily, the concern is that candidates with cardiomyopathy, who do relatively well post-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 that 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 explicitly including this group 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- those that do not meet the criteria defined in policy could always request 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.

Another question was raised as to why heart candidates less than one year of age with hypertrophic cardiomyopathy were included in the pediatric Status 1B criteria. The Committee member stated that he was familiar with data that would support including these young, restrictive cardiomyopathy heart candidates, but he was not familiar with data that focused on candidates less than one year of age with hypertrophic cardiomyopathy. The Committee's Thoracic Committee crossover representative explained that the data reviewed during

discussions about these policy changes did not show increased waiting list mortality for those restrictive and hypertrophic cardiomyopathy patients that are older than one year of age.

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 UNet^{SM} functionality that requires interested 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 Memorandums

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 that 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. Those programs that are considered "small-volume centers" have every graft failure and transplant recipient death within one year of transplant reviewed since there is no statistical measure to evaluate these programs. This results in a number of cases that must be reviewed by the MPSC. Additionally, because of the low volumes at the center, the MPSC often has difficulty making a judgment about the outcomes at that center. This situation 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 that detailed its discussion about a memorandum that the Committee sent regarding an apparent discrepancy between policy and programming that pertains to inactive Priority 1 lung candidates. UNOS staff informed the Committee that the apparent discrepancy 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 UNet℠ 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.

OPTN/UNOS Pediatric Transplantation Meeting

September 6, 2012
Chicago, Illinois

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