

**OPTN/UNOS Pediatric Transplantation Committee**  
**Report to the Board of Directors**  
**June 25-26, 2012**  
**Richmond, Virginia**

**Summary**

**I. Action Items for Board Consideration**

- None

**II. Other Significant Items**

- The Committee discussed adding pediatric transplantation experience considerations in the bylaws. (Item 1, Page 3)
- The Committee discussed OPTN Final Rule requirements for organ allocation policy development. (Item 2, Page 5)
  - Thoracic Organ Allocation Policy Review (Item 2a, Page 5)
  - Kidney Allocation Policy Review (Item 2b, Page 8)
  - Liver Allocation Policy Review (Item 2c, Page 10)
- The Committee considered policy and bylaw proposals distributed for public comment. (Item 3, Page 11)
  - Proposals issued on September 16, 2011 (Item 3a, Page 11)
  - Proposals issued on March 16, 2012 (Item 3b, Page 13)

**OPTN/UNOS Pediatric Transplantation Committee**  
**Report to the Board of Directors**  
**June 25-26, 2012**  
**Richmond, Virginia**

**David N. Campbell, M.D., Chair**  
**Heung Bae Kim, M.D., Vice Chair**

*The following report presents the OPTN/UNOS Pediatric Transplantation Committee's deliberations and recommendations on matters considered during its December 9, 2011, and March 19, 2012, meetings.*

1. Addition of Pediatric Transplantation Experience Considerations in the Bylaws

The Pediatric Transplantation Committee's (the Committee) organ-specific working groups have each discussed potential pediatric experience criteria for primary physicians and primary surgeons. Based on previous Committee feedback, these initial discussions were had with the intent that any transplant program intending to transplant pediatric patients must have staffing who meet established criteria. Some concerns with this overarching approach were noted, and each working group discussed these concerns and what it felt the scope of this effort should be with the understanding that this topic would be discussed by the full Committee at its March 2012 meeting. To help facilitate the full Committee's discussion, UNOS staff provided a historical account of the recent events that led to the Committee's focus and discussion on this topic.

The Committee does not believe data are presently available that directly link good outcomes and quality care to minimum experience criteria; but, it seems reasonable to infer that competence is more likely with repetition and increasing experience. The Committee believes that those leading a transplant program at a children's hospital should have pediatric transplant experience – yet this is not a set expectation. Committee members noted that current primary surgeon/physician requirements in the bylaws were developed with minimal data, but the community ultimately supported those recommendations, and members are strictly held to these requirements. Committee members reiterated once again that limiting access for pediatric transplant candidates is not the goal; rather, the goal is to establish a baseline of requirements to assure that pediatric transplant candidates are receiving the appropriate care for their unique medical condition. The Committee understands that policy proposals must be evidence-based, but there are different types of evidence- the Committee's expertise being one such type. Without robust quantitative data, it seems that thoughtful recommendations from the Committee will be the best piece of evidence that can be put forth. As such, the requirements bar will have to be set relatively low so that the requirements do not exclude qualified clinicians.

Committee members believed that establishing baseline pediatric criteria will formally codify that pediatric transplantation requires caretakers with a unique set of skills. Having such criteria would then force children's hospitals to consider if they are prepared to start a transplant program for a specific organ. Additionally, the Committee also thought that established pediatric experience criteria may make transplant programs that primarily transplant adult candidates reconsider undertaking unique and challenging pediatric cases. Committee members stated that to cease work on these efforts due to low volumes and the inability to produce statistically significant data to support any recommended minimal requirements would indicate passive support of the bylaws' current silence on pediatric transplantation experience. Such passive support conflicts with the Committee's opinion that minimal requirements need to be set for key personnel who care for pediatric transplant patients.

The Committee discussed sending a survey to evaluate the experience of clinicians currently serving in these leadership roles at pediatric hospitals. The information obtained could be pared down to a mean

level of experience that could then be used for the requirements. Such a survey will give insight into these professionals' current experience, not their experience when they began serving in these leadership roles. Any pediatric experience requirements would set a minimum level of expectations, and a survey probing into current experience would not be very insightful to this point. Another approach would be to survey those programs that have had a recent key personnel change, but this may not provide a sufficient sample. Ultimately, the idea of survey did not gain much traction.

Acknowledging the difficulty in proving a strong correlation between minimal case volume experience and competency, a Committee member suggested that the requirement could be that a candidate proposed to fill a key personnel role must have a current supervisor write a letter that attests to the competency and experience of the individual. Committee members were hesitant to support this as the sole requirement. Although the Committee believes that most would earnestly undertake this task, there were concerns that personal relationships could yield biased letters. Committee members indicated that these letters of recommendation could be valuable as one component of any potential criteria.

Technical skill is important to consider, but the judgment of a pediatric primary surgeon or physician is also important, if not more so. There are additional complexities with pediatric cases, and the diseases that precipitate a child's need for transplant are not the same as those diseases that commonly ail adult transplant patients. Committee members stated that case numbers alone will not necessarily reflect one's judgment, and a letter of recommendation could accommodate this consideration.

The Committee discussed the scope of this project forward. A Committee member stated that she believed the Committee should first focus on those centers that primarily transplant pediatric patients, defining a "pediatric center" as one that transplants patients younger than 18 years of age more than 50% of the time. Bylaw requirements should mandate that the leadership at those centers have a certain level of pediatric experience. She did not believe that the Committee would be able to develop recommendations that would be accepted by the transplant community that regulate every center intending to transplant all patients under the age of 18. It was her opinion that the establishment of requirements that focused on those centers that primarily transplant pediatric patients would naturally result in more complicated cases being referred to these pediatric hospitals as they would then be explicitly and formally recognized as having professionals that specialize in pediatric transplantation. Committee members commented that taking this approach would likely be more readily accepted by the transplant community. Committee members opined that moving towards this goal deliberately and in a stepwise fashion would be better than trying to address this issue with one potentially contentious proposal, which could ultimately result in the status quo continuing with no requirements being set.

Alluding to large centers that do a significant number of pediatric transplants, with adult transplants representing the majority of the transplants performed, Committee members expressed concern that these centers would not be expected to meet the same standards. As such, these Committee members felt that the pediatric patient population at those centers may not be as well served. Committee members responded that there is no mechanism currently to separate these larger centers into pediatric and adult entities. Separating these centers into pediatric/adult distinctions and creating new key personnel roles is an option that could be pursued, but some Committee members reiterated their concerns that recommending this more complex solution would not be well received among the transplant community. Committee members suggested focusing on those centers that primarily transplant pediatric patients as a first step. Once those requirements are established, the impact and effectiveness of these requirements can be evaluated. Successful efforts that focus on transplant centers primarily transplanting pediatric patients could then be used as a foundation to develop a broader set of recommendations.

Committee members pointed out a few risks with these requirements. If the requirements are too stringent, then the proposal won't be adopted. If the requirements are not restrictive enough, then the requirements do not have as much impact. There is also a risk that administrators of children's hospitals will not vet candidates to lead transplant programs as carefully if the candidate meets the established bylaw requirements. Committee members acknowledged that setting specific case volumes does have some flaws. Some of these same flaws are also present on the adult side; however, the key personnel bylaw requirements are well accepted at this point and have yielded more benefit than harm. As such, Committee members replied that now is the time to introduce pediatric-specific requirements for pediatric centers, and by doing so, formally recognize the unique nature of caring for pediatric transplant candidates and recipients.

Considering the debate thus far, the Chair wanted the Committee to vote if it should continue to work on these efforts to gauge the ongoing level of support for this project. The Committee supported a motion (17 support, 1 oppose, 1 abstention) that the Committee set some minimum numbers of pediatric experience to qualify to be a pediatric primary surgeon or physician. The Committee is pursuing these efforts because it recognizes that the care necessary for pediatric transplant candidates and recipients is unique and different than the care necessary for adult transplant candidates and recipients.

Committee members recommended that these requirements primarily focus on experience and training with handling the most challenging types of cases for each particular organ group, not just a requirement for a set number of pediatric transplants. A question was raised if transplant programs would be expected to meet the current bylaw requirements in addition to the pediatric experience requirements? The goal is to assure key personnel at pediatric transplant hospitals have pediatric transplantation experience. The Committee agreed that it would be most important for key personnel to meet the pediatric-specific requirements that the Committee aims to develop.

Committee members asked if the bylaws have defined what entails a "pediatric center." UNOS staff replied that there is not a formal definition, noting the current language in the bylaws that incorporates the "pediatric pathway" applies to, "transplant programs serving predominantly pediatric patients." This reference to the "pediatric pathway" yielded additional comments supporting the Committee's focus on those centers that primarily transplant pediatric candidates. Instead of petitioning the Membership and Professional Standards Committee (MPSC), and having a few of its members review the candidate's qualifications, the Committee, with extensive pediatric representation, should determine requirements that the MPSC can definitively use for key personnel at these pediatric centers. Committee members reiterated that drafting requirements to modify the pediatric pathway would likely be more readily accepted in the community. The intent of this pathway must be modified so that it is not solely an option, but so that it is required for those centers that primarily transplant pediatric patients. The Committee concluded its discussion by directing the Working Groups to focus on organ specific recommendations to be included in the bylaws for key personnel at those centers that primarily transplant pediatric patients.

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

### 2a. Thoracic Organ Allocation Policy Review

*December 14th Teleconference with Heart Subcommittee of the Thoracic Committee- Continue Pediatric Heart Policy Review Update-* At its March 2012 meeting, the Chair provided an update on the Thoracic Working Group's efforts to update and modify pediatric heart allocation policy. These efforts are being undertaken along with members of the Heart Subcommittee of the Thoracic Organ Transplantation Committee (the Thoracic Committee). The Committee reviewed potential

changes that are being discussed, which include redefining the Status 1A and Status 1B criteria for pediatric heart candidates, modifying the eligibility criteria for an ABO-incompatible heart transplant, modifying the allocation priority of ABO-incompatible heart potential transplant recipients, and eliminating the option to list heart candidates as *in utero*. Specifically, the tentative recommendations for pediatric heart Status 1A criteria are:

- a) Requires assistance with a ventilator;
- b) Requires assistance with a mechanical circulatory support device;
- c) Requires assistance with an intra-aortic balloon pump;
- d) Has ductal dependent pulmonary or systemic circulation with ductal patency maintained by stent or prostaglandin infusion;
- e) Has a congenital heart disease diagnosis (excluding minor lesions such as atrial septal defect, ventricular septal defect, PDA, or bicuspid aortic valve); is admitted to the listing center hospital; and, requires infusion of high dose or multiple inotropes; or
- f) By exception

For pediatric heart Status 1B:

- a) Has a diagnosis of cardiomyopathy and requires infusion of one or more intravenous inotropic agents;
- b) Has a diagnosis of congenital heart disease and requires infusion of low dose single inotrope; or
- c) By exception

Regarding ABO-incompatible heart transplants, the tentative recommendation is to increase the qualifying isohemagglutinin titer level to 1:16, and prioritize qualified ABO-incompatible heart potential transplant recipients with those in each respective “secondary ABO” match run classification.

A Committee member asked how the new, proposed Status criteria will impact pediatric heart candidates’ Status 1A/Status 1B/Status 2 distribution. There are not data to formally model the recommendations. Based on the data reviewed by the Working Group, it is believed that these proposed changes will impact heart allocation so that urgency is a more prominent factor. Specifically, the recommendation to list cardiomyopathy patients who require inotropic infusions as Status 1B is anticipated to decrease significantly the number of pediatric heart candidates who are waitlisted as Status 1A at any given time.

The Committee was reminded that these recommendations are intended to be distributed for public comment in the fall, and may be adjusted in the interim.

*Evaluation of ABO-Incompatible Heart Policy*- UNOS Research support for the Committee, Wida Cherikh, Ph.D., presented an analysis of the impact of the ABO-incompatible heart policy changes that were implemented in November 2010. To summarize the results of the analysis:

- Only 34% of the 195 non-AB registrations added to the heart alone waiting list before the age of 2 years and in Status 1A or 1B at listing indicated a willingness to accept a heart of an incompatible blood type.
- Of the pediatric registrations less than two years old at the time of listing with a non-AB blood type and a medical urgency status of 1A or 1B and are still on the heart alone waiting list as of January 31, 2012, 37% were willing to accept a heart of an incompatible blood type.
- None of the candidates listed between the ages of 1 and 2 indicated a willingness to accept an ABO-incompatible heart.

- All 16 ABO-incompatible heart alone transplants during 11/22/10-11/21/11 were performed in recipients less than a year old at both listing and transplant.
- Of the 16 recipients of ABO-incompatible heart alone transplants performed in the year following policy implementation, one recipient died at 51 days post-transplant with “cerebrovascular” noted as the primary cause of death. At time of death, the titer value was reported to be 1:2.

*Evaluation of Broader Sharing of Lungs from 0-11 Year Old Donors and Simple Priority System for 0-11 Year Old Lung Candidates* – UNOS Research staff presented an analysis of policy changes implemented in September 2010 that introduced broader sharing of lungs from 0-11 year old donors, and the establishment of a two-tier priority system for lung candidates that are younger than 12 years of age. To summarize the results:

- The number and percentage of pediatric additions to the lung waiting list aged 0-11 and 12-17 decreased during the 14 months following policy implementation, although overall number of additions increased post-policy.
- Over half (62%) of the pediatric additions aged 0-11 during the 14 months post-policy were listed in Priority 1.
- On January 31, 2012, 33% of registrations aged 0-11 were waiting in Priority 1.
- Across all donor age groups, there was not much change in the distribution of deceased donor lung dispositions during the 14 months post-policy as compared to the 14 month period pre-policy.
- The total number of lung transplants performed in recipients aged 0-11 and 12-17 decreased following policy implementation.
- The percentage of Zone B transplants performed in 0-11 years old recipients from 0-11 years old donors has increased since policy implementation.
- During 14 months post-policy implementation, 21 out of the 22 recipients aged 0-11 received their lung alone transplant from 0-11 years old donors in Priority 1, most of which were Zone B transplants.
- There was no significant change in death or transplant rate post- vs. pre-policy for any age group.

The Committee observed that the increase in Zone B transplants is an encouraging, expected result from these policy changes. The Committee also commented on the absence of change in death rates relative to broader sharing of lungs from 0-11 year old donors that should expand the number of offers 0-11 year old lung candidates receive. The Committee noted that there were adult candidates transplanted with lungs from 0-11 year old donors, but no 0-11 year old lung candidates transplanted with lungs from an adult donor. Adult candidates being transplanted with these donor lungs is not problematic as it is likely that there were no 0-11 year old lung candidates actively listed in each respective geographic region when these transplants occurred. The concern is that when these candidates are actively listed, and there is an adult donor who may be appropriate (e.g. small statured donor for a 9 year old lung candidate), they are unlikely to receive an offer because these potential transplant recipients are prioritized after those potential recipients 12 and older that are ordered by their lung allocation score (LAS), even if the 0-11 year old candidate is a more urgent case. Attempts to address this phenomenon may impact the death rate; however, it was stated that any allocation modification would likely yield only a couple of 0-11 year old lung candidates transplanted with adult donor lungs in any given year.

The Committee will continue to review these data on an ongoing basis.

## 2b. Kidney Allocation Policy Review

*Update- Memo to Kidney Committee RE: Criteria for Pediatric Kidney Candidates to Accrue Waiting Time-* The Committee was reminded of its September 2011 discussion about minimal criteria for pediatric kidney candidates to begin accruing waiting time. This discussion ended with a motion to send a memo to the Kidney Transplantation Committee (Kidney Committee) that suggested potential criteria for pediatric candidate's to accrue waiting time, including a mechanism to review any unique pediatric kidney candidates that did not meet this threshold. Subsequent to this meeting, the Kidney Working Group further discussed these recommendations. During this later discussion, the Kidney Working Group recognized that establishing minimal GFR criteria for pediatric kidney candidates to begin accruing waiting time will not address the perceived issue regarding preemptive listing for pediatric priority- candidates could still be listed and would appear on match runs without having accrued any waiting time. Additionally, a review system for cases not meeting the threshold (which the Committee believes is necessary) would add more complexity to the system and likely require significant resources relative to the few numbers of cases needing review. Furthermore, the data reviewed at the Committee's September 2011 meeting that analyzed the latest pediatric data (2006-2007) for preemptive kidney listings showed GFR>30 ml/min/1.73m<sup>2</sup> listings are spread across all age groups, with the highest percentage (relative to all preemptive listings in each respective age group) appearing in the 14 year old age group, not the 17 year old age group.

Considering this discussion, the Kidney Working Group recommended that the Committee send a memo to the Kidney Committee that recommended no policy changes regarding pediatric kidney candidates' accrual of waiting time. The Committee then reviewed a memo that had been drafted to communicate this message. Ultimately, the Committee unanimously supported a motion (21 support, 0 oppose, 0 abstentions) to support the Kidney Working Group's recommendation to send the updated memo.

*Update on a Potential Regional Sharing System for Highly Sensitized Pediatric Kidney Candidates-* The Committee was updated on the Kidney Working Group's ongoing discussions with members of the Kidney and Histocompatibility Committees. To summarize those discussions:

- Call participants explored what would define "highly sensitized" for this allocation system. It was assumed that the 80% threshold would be used, but there were questions if that was the correct value. An earlier pediatric data analysis of the number of pediatric candidates added to the kidney waiting list over a 20 month period (ending 5/31/2011) by their CPRA at listing showed 33 candidates listed with a CPRA  $\geq$ 80%. Call participants agreed that a CPRA of 80% or greater should be the threshold for any pediatric priority that is granted due to the candidate's immunological sensitivity. Call participants have also requested an analysis to verify that the anticipated impact, which considered PRA, is consistent in the transition to CPRA.
- An explicit goal of this project is to minimize the number of positive crossmatches that occur after the shipment of the kidneys. With guidance from members of the Histocompatibility Committee, call participants felt confident that CPRA would work effectively if all available sensitivities are reported, including some that are not currently collected by the OPTN. The system should also include a review process of those positive crossmatches to promote additional, ongoing efforts to minimize the number positive crossmatches realized after a kidney has been shipped.

- Reallocation of the kidney in the event of a positive crossmatch continues to be considered. It is possible that the Host OPO, and the transplant centers served by that OPO, would want the kidney shipped back to be reallocated locally. The only solution raised thus far is to provide the Host OPO the option of having the kidney shipped back, though such a policy element may not be as reasonable in more geographically dispersed regions.

A Committee member asked if this additional priority would be above those receiving multi-organ transplants, specifically simultaneous kidney-pancreas transplants. Members of the Kidney Working Group responded that this priority is only intended to apply to isolated kidney allocation—the primary advantage being prioritizing highly sensitized pediatric kidney potential recipients that are in the region above the prioritized, highly sensitized, adult kidney potential recipients. The Committee member replied that the root of his question is a concern that a non-sensitized kidney-pancreas transplant recipient would receive a kidney that would otherwise be suitable, and allocated to, a highly-sensitized, pediatric candidate waiting for an isolated kidney. Other Committee members echoed the concerns, and expressed similar thoughts in the spring of 2010 when the Pancreas Transplantation Committee (Pancreas Committee) was seeking comment on its proposal to modify pancreata allocation. Although the Pancreas Committee was aware of the concern, modeling results indicated that the proposed changes would not significantly impact pediatric kidney transplantation. As such, it was challenging for the Committee to build much support for its concerns. During this March 2012 discussion, the Committee hypothesized that the number of pediatric kidney transplants is not large in a nationwide analysis to reflect these concerns. Committee members suggested analyzing transplant rates and the average time spent on the waiting list for pediatric kidney candidates in regions with large kidney-pancreas programs as compared to those in regions with smaller kidney-pancreas programs. Recognizing that the new pancreas allocation system has been adopted by the OPTN/UNOS Board of Directors and is waiting implementation, the Committee was asked to be mindful of this in the future and propose changes if data encourage action.

*KPSAM Analysis of Allocation Changes Using CPRA*- Representatives from the Scientific Registry of Transplant Recipients (SRTR) presented Kidney-Pancreas Simulated Allocation Model (KPSAM) results requested by the Kidney Working Group. As discussed above, the KPSAM was requested to verify that regionally sharing kidneys for highly sensitized pediatric candidates would produce similar results considering CPRA, as compared to past analyses use of PRA.

For this data request, the acceptance models were updated using 2010 OPTN match run data, KPSAM input files were updated using 2010 candidates and organ arrivals with CPRA for allocation, and results were averaged across 10 iterations. To summarize the results, the following conclusions were made with respect to the current allocation system:

- For zero mismatch allocation, giving priority to highly sensitized pediatric candidates over adult candidates resulted in almost no change in the transplant count from the baseline run.
- For non-zero mismatch allocation, regional sharing for highly sensitized pediatrics resulted in an increase in transplant number and a shift in transplants from local pediatrics to regional pediatrics.
- Increase in regional transplants was seen in donors <35 yrs.
- Regional sharing of older donors for highly sensitized pediatrics would not seem to notably increase transplants.

Committee members commented that these data are similar to past analyses using PRA. Committee members also stated that though these numbers are relatively small as compared to annual kidney transplants, the magnitude of the changes it is pursuing are anticipated to significantly impact the number the highly sensitized pediatric kidney candidates on the waiting list.

## 2c. Liver Allocation Policy Review

*Split Liver Allocation Modification-* The Chair updated the Committee on feedback he received regarding the split liver concept the Committee has been developing. Upon updating the Board of Directors at its November 2011 meeting on the Committee's recent and ongoing efforts (including the split liver concept) the President recommended that these split liver efforts be tabled. This recommendation was due in part to the Board of Directors' earlier, unanimous adoption of a split-liver, Committee-Sponsored Alternative Allocation System (CAS) that was sponsored by the Liver and Intestinal Organ Committee (the Liver Committee). The President indicated that it would not be prudent to pursue additional split-liver allocation modifications until the impact of the CAS could be analyzed. With respect to this recommendation, the Committee agreed to table its current efforts to modify split liver allocation. Also with respect to the recommendation, the Committee expressed a desire to review annual results of the CAS. This review should begin with, and continue to include, the results of the Region 2 and OneLegacy split-liver alternative allocation systems that served as precursors to the split-liver CAS. Specifically, the Committee wants to review the number of these types of allocations and subsequent transplants that have occurred, the outcomes of those transplants, and the number of pediatric patients on the original match run within the OPO or region (depending on the framework of that particular alternative allocation system) that were prioritized above the recipient of the second liver segment and not given an organ offer.

*Evaluation of Broader Sharing of Livers and Liver-Intestines From 0-10 Year Old Donors-* UNOS Research staff presented an impact analysis of policy changes that more broadly shared livers and liver-intestines from 0-10 year old donors, which was implemented on November 2010. To summarize the findings of the analysis:

- After policy implementation, the number and percentage of all liver alone transplants performed in 0-11 years old recipients from 0-10 years old donors increased.
- The number of Status 1A liver alone transplants performed in 0-11 years old recipients from 0-10 year old donors increased almost 3-fold, from 16 pre-policy to 43 post-policy.
- Although the number of liver-intestine transplants from 0-10 years old donors went down from 41 to 31 following policy implementation, the percentage transplanted into 0-11 year old recipients increased from 91% to 97%.
- There was no increase in the percentage of livers and intestines recovered and transplanted from 0-10 years old donors post-policy and a slight decrease in the percentage of 0-10 years old and 11-17 years old livers discarded.
- Although not statistically significant, there was a decrease in waiting list death rate during the 10 months following policy-implementation, both overall and in Status 1A, for all pediatric age groups.
- There was a significant increased transplant rate in Status 1A for liver alone candidates aged 0-11 at listing.

### 3. Review of Policies and Bylaws Issued for Public Comment

#### 3a. Proposals issued on September 16, 2011

Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors- The vice chair of the Living Donor Committee, Amy Waterman, Ph.D., joined the teleconference to present the Living Donor Committee's proposals. After Dr. Waterman presented the proposal, a Committee member asked if a center's informed consent procedure was expected to incorporate the policy language verbatim. Dr. Waterman clarified that the policy provides minimal elements that must be included, but does not necessarily need to be copied exactly. In response to another question, Dr. Waterman clarified that these requirements are only for living kidney donors; however, policy for living liver donors is anticipated in the future.

Without any further questions or discussion, the Committee unanimously voted in favor of the proposal as drafted (14-support, 0-oppose, 0-abstentions).

Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors- After Dr. Waterman presented this proposal, a Committee member clarified that these policies aim to establish minimal requirements. Dr. Waterman also indicated that if these policies are adopted, centers would be responsible for these requirements for potential living kidney donors whose initial evaluation begins on or after the implementation date. Those living donors that have already begun the living donor assessment process prior to the implementation date would not be reviewed for compliance with these requirements.

Without any further questions or discussion, the Committee unanimously voted in favor of the proposal as drafted (14-support, 0-oppose, 0-abstentions).

Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-Up- Dr. Waterman presented the Living Donor Committee's third proposal.

The Committee indicated support for the concept of the proposal but has a few concerns with what is being proposed:

- The Committee was concerned that a simple 90% threshold could result in centers with small volumes of living donors being out of compliance with just one incomplete form, regardless of the center's diligence in following-up with its living donors (e.g. If the center is following four living donors, one incomplete form yields 75% form completion). To account for this, the Committee suggests determining a confidence interval for the 90% compliance threshold (or some other measure) to consider a center's volume in their compliance with this policy.
- The Committee is also concerned with the difference between current compliance rates and the expectations in this policy proposal. There is concern about members' ability to comply immediately with these requirements. A suggestion to help members' compliance is a progressive increase over a few years in the expected percentage of completed living donor follow-up forms, with the requirement eventually being set at 90%.
- The Committee recognizes that incomplete forms are sometimes because the living donor is not cooperative with the follow-up process. As such, the Committee is concerned with transplant centers being out of compliance in spite of their best efforts. To account for these donors that refuse to participate in the follow-up process, the Committee suggests including a response that would be considered a "complete" answer that indicates that follow-up had been pursued, but declined by the living donor. This response option

should only be available for those questions that require explicit donor cooperation, such as obtaining laboratory values.

The Committee unanimously voted to support this proposal, along with communication of these three concerns and suggestions for the Living Donor Committee's consideration. (14-support, 0-oppose, 0-abstentions)

Proposal to Extend the "Share 15" Regional Distribution Policy to "Share 15 National" & Proposal For Regional Distribution of Livers for Critically Ill Candidates– The Committee Vice Chair presented the proposal for discussion.

A Committee member asked if the candidate's calculated MELD/PELD score or MELD/PELD score including exceptions would be used for this allocation algorithm. If "Share 15 National" uses scores with exceptions, it was predicted that numerous exceptions will be submitted to get a score above 15. Noting that standard exceptions would be included for "Share 35 National," the Committee was unclear where PELD candidates with scores above 40 would appear on the match run.

A Committee member asked how this allocation change may affect adolescent liver candidates. Discussion indicated that the "Share 35 Regional" changes would benefit liver candidates with elevated MELD/PELD scores, including adolescents. Similarly, those with MELD/PELD scores less than 35, including adolescents, will be lower on the match run. The Committee expressed some concern about adolescents that didn't have elevated MELD scores, as their generally lower creatinine values result in lower MELD scores. Sensitive to these concerns, other Committee members commented that the magnitude of the impact from these policy changes is probably not great enough to show a significant effect on adolescent candidates.

The Committee unanimously voted to support the "Share 35 Regional" proposal, with a request that the Liver Committee clarify how candidates with a PELD score greater than 40 will be prioritized in this allocation algorithm. (14-support, 0-oppose, 0-abstentions)

Additionally, the Committee unanimously voted to support the "Share 15 National" proposal as written. (14-support, 0-oppose, 0-abstentions)

Plain Language Modifications to the Adult and Pediatric Heart Allocation Policies, Including the Requirement of Transplant Programs to Report in UNet<sup>SM</sup> a Change in Criterion or Status within Twenty-Four Hours of that Change– UNOS staff presented this proposal for the Committee. After minimal discussion, the Committee unanimously voted to support the proposal as written. (13-support, 0-oppose, 0-abstentions)

Proposed Revisions to and Reorganization of Policy 6.0 (Transplantation of Non-Resident Aliens), Which Include Changes to the Non-Resident Alien Transplant Audit Trigger Policy and Related Definitions– The UNOS liaison to the Ad Hoc International Relations Committee presented the proposal for the Committee. A Committee member from a border state indicated that she thought the policy would be helpful, mentioning current measures in place at her center to keep the transplant rate of non-citizen, US residents below 5%. She felt this proposal would increase these candidates access, but felt it did not adequately address "transplant tourism." Considering the limited number of donors, she recommended measures be put in place to limit the number of non-citizen, non-resident transplants. Another Committee member expressed concerns about potential negative responses from the public, directed at centers for transplanting patients

addressed in the proposal, if data that will be collected is interpreted or presented in a sensational manner. Another Committee member commented on the potential that the questions outlined in the proposal could easily be answered deceptively, and questioned if stricter definitions could curtail this. UNOS staff indicated that this is a concern, and numerous parties have pointed this out.

A motion was made to support the proposal with a request that the Ad Hoc International Relations and Ethics Committees consider including a more comprehensive review process for, or limit the number of, non-US resident, non-US citizen transplants. The Committee supported this proposal. (11-support, 1-oppose, 1-abstention)

*Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions-* After minimal discussion, the Committee unanimously voted in favor of a motion to support the proposal as written. (11-support, 0-oppose, 0-abstentions).

### 3b. Proposals issued on March 16, 2012

*Proposal to Revise the Lung Allocation Score System-* A member of the Thoracic Committee presented this proposal for the Committee. After minimal discussion, the Committee unanimously voted to support the proposal as written (21 support, 0 oppose, 0 abstentions).

*OPTN Bylaws Substantive Rewrite of Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs-* UNOS staff that supports the MPSC presented the proposal for the Committee. After minimal discussion, the Committee unanimously voted to support the proposal as written (20 support, 0 oppose, 0 abstentions).

*Proposal to Establish Kidney Paired Donation (KPD) Policy-* UNOS staff managing the UNOS KPD program presented the proposal for the Committee. After minimal discussion, the Committee unanimously voted to support the proposal as written (20 support, 0 oppose, 0 abstentions). Following this vote, the Committee requested a resource for members that specifically lists what would be audited for these policies and how members are expected to comply.

*Proposal to Include Bridge Donors in the OPTN Kidney Paired Donation Program-*The Committee reviewed the second kidney paired donation proposal which introduces bridge donors to the KPD program. After minimal discussion, the Committee voted to support the proposal as written (18 support, 0 oppose, 1 abstention).

*Proposal to Require Reporting of Unexpected Potential or Proven Disease Transmission Involving Living Organ Donors-* The liaison to the Living Donor Committee presented the proposal for the Committee. After minimal discussion, the Committee unanimously voted to support the proposal as written (19 support, 0 oppose, 0 abstentions).

*Proposed Changes to the Donation after Cardiac Death (DCD) Model Elements-* The liaison to the Organ Procurement Organization (OPO) Committee presented the proposal for the Committee. After minimal discussion, the Committee unanimously voted to support the proposal as written (19 support, 0 oppose, 0 abstentions).

*Proposal to Clarify Priority Status for Prior Living Organ Donors who Later Require a Kidney Transplant-* The Committee's crossover representative to the Kidney Committee presented the proposal for the Committee. After minimal discussion, the Committee unanimously voted to support the proposal as written (19 support, 0 oppose, 0 abstentions).

OPTN/UNOS Pediatric Transplantation Meeting  
December 9, 2011  
Teleconference

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

OPTN/UNOS Pediatric Transplantation Meeting  
 March 19, 2012  
 Chicago, Illinois

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