

**OPTN/UNOS Pediatric Transplantation Committee**  
**Report to the Board of Directors**  
**November 14-15, 2011**  
**Atlanta, Georgia**

**Summary**

**I. Action Items for Board Consideration**

- The Board of Directors is asked to approve modifications to Policy 3.6.4.2 (Pediatric Candidate Status). The proposed changes eliminate the requirement that a pediatric Status 1A or Status 1B liver candidate must be located in the hospital's intensive care unit. (Item 1, Page 3)
- The Board of Directors is asked to approve modifications to Policy 3.6.4.2 (Pediatric Candidate Status) and the deletion of Policy 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma). These proposed changes will permit Status 1B listings for all candidates with hepatoblastoma proven by biopsy, and without evidence of metastatic disease at the time of listing. (Item 2, Page 3)

**II. Other Significant Items**

- The Committee discussed OPTN Final Rule requirements for organ allocation policy development. (Item 4, Page 5)
  - Kidney Allocation Policy Review (Item 4a, Page 5)
  - Thoracic Organ Allocation Policy Review (Item 4b, Page 8)
  - Liver Allocation Policy Review (Item 4c, Page 14)
- The Committee discussed adding pediatric transplantation experience considerations in the bylaws. (Item 5, Page 17)

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**OPTN/UNOS Pediatric Transplantation Committee**  
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**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 July 20, and September 27, 2011, meetings.*

**I. Action Items for Board Consideration**

1. Eliminate the Intensive Care Unit Requirement for Pediatric Status 1A and Status 1B Liver Candidates- During its July 2009 meeting, the Pediatric Transplantation Committee (the Committee) discussed a memorandum it received from the Membership and Professional Standards Committee (MPSC). Regarding the requirement in Policy 3.6.4.2 (Pediatric Candidate Status) that a “pediatric candidate listed as Status 1A or 1B is located in the hospital’s Intensive Care Unit (ICU),” the MPSC expressed concern that the policy uses a candidate’s location as a surrogate for severity of illness, and asked the Committee to discuss whether this remains advisable and appropriate.

The Committee agreed with the MPSC’s sentiments and commented that the ICU requirement likely yields inconsistent listings as conditions for admittance to an ICU varies across institutions. In addition, Committee members indicated it is not uncommon for pediatric liver candidates that are not in the ICU to be listed as Status 1A or 1B through submission of a special case.

After discussions with the Liver and Intestinal Organ Transplantation Committee (the Liver Committee) which ultimately indicated support, the Committee submitted policy modifications for public comment that would remove the ICU requirement for pediatric Status 1A and 1B liver candidates. The Committee reviewed the feedback this proposal received at its July 20, 2011, meeting. Considering the comments were predominately in support, the Committee unanimously supported (18-support, 0-opposed, 0-abstentions) a motion to submit the following resolution for the Board’s consideration:

**\*\* RESOLVED, that the modifications to Policy 3.6.4.2 (Pediatric Candidate Status), as set forth in Exhibit A, are hereby approved, effective pending notice to the membership.**

The briefing paper and resource assessment and impact statement for this proposal can be found in **Exhibit B and C**, respectively.

2. Candidates with hepatoblastoma permitted to be listed as Status 1B- At its July 2009 meeting, a Liver Committee member asked it to consider if Policy 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma) is still appropriate. This question stemmed from the perception that the majority of pediatric candidates with hepatoblastoma are transplanted at Status 1B, and the initial listing of these patients at a MELD/PELD score of 30 for 30 days- as currently dictated by policy- acts as a delay to transplantation. The Committee also discussed this issue at its July meeting. Both

committees agreed that this matter deserved attention and recommended that the joint Pediatric/ Liver and Intestine Subcommittee review it further.

After reviewing nearly four years of data that analyzed candidates on the waiting list with hepatoblastoma, the Committee felt that policy should be modified so that these candidates may be immediately listed as Status 1B; thereby eliminating the current requirement that these candidates must be listed at a MELD/PELD score of 30 for 30 days prior to being upgraded to Status 1B. With the Liver Committee's support, the Committee submitted this recommendation for public comment consideration.

The Committee reviewed the feedback to this proposal at its July 20, 2011, meeting and the comments were predominately in support. Considering the support for the ICU proposal that was also distributed for public comment, the Committee made minor changes to the proposed policy language to align the proposed modifications of both proposals. The Committee unanimously supported (18-support, 0-opposed, 0-abstentions) a motion to submit the following resolution for the Board's consideration:

**\*\* RESOLVED, that the modifications to Policy 3.6.4.2 (Pediatric Candidate Status) and Policy 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma), as set forth in Exhibit D, are hereby approved, effective pending notice to the membership.**

The briefing paper and resource assessment and impact statement for this proposal can be found in **Exhibit E and F**, respectively.

## **II. Other Significant Items**

3. Committee Review of Potential Policy Language Modifications to Policy 7.1 (Reporting Definitions). The Organ Procurement Organization (OPO) Committee had requested the Committee's input on potential policy language modifications regarding imminent and eligible death definitions. The Committee invited OPO Committee representatives to participate on its July 2011 teleconference meeting to review these potential modifications.

The Committee's discussion primarily focused on the low weight threshold, asking how the OPO Committee determined that value to be 5kg, and suggesting that 3kg may be more appropriate. OPO Committee representatives stated that data describing imminent and eligible donors were reviewed, and there were very few examples of donors that weighed less than 5kg. After considering a few lower weight thresholds, the OPO Committee elected to use 5kg to reduce the data burden that would result from the number of cases that would fall below the 5kg lower threshold, but that rarely yield a donor. Although these definitions are strictly intended for reporting purposes and would not prevent an OPO from pursuing a donor outside of these definitions, a Committee member expressed concern that OPO's not being held accountable for donors of this size could result in an unintended consequence of OPO's not pursuing these donors. OPO representatives indicated that ignoring potential donors less than 5kg would be counter-productive for the OPO, and therefore the Committee member's concern likely isn't valid in reality. With these explanations, the Committee did not object to the 5kg weight threshold, and expressed its appreciation of the OPO Committee's data burden considerations while drafting these policy modifications.

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

##### 4a. Kidney Organ Allocation Policy Review

August 19th Kidney Working Group Teleconference with the Histocompatibility and Kidney Transplantation Committees: Ongoing Consideration of Regional Sharing for Highly-Sensitized Pediatric Kidney Candidates- At its September meeting, the Committee received an update on an August teleconference the Committee's Kidney Working Group had with members of the Kidney Transplantation Committee (Kidney Committee) and the Histocompatibility Committee. During the call, participants reviewed data showing the distribution of highly-sensitized candidates that are currently waiting among the different regions. There is some variation in the distribution of these candidates across the regions, but the total numbers are relatively small. This led call participants to conclude that the current OPTN/UNOS regional boundaries would be sufficient to define what constitutes a "region" for the purposes of this allocation trial.

Call participants also discussed how best to avoid positive crossmatches. Representatives from the Histocompatibility Committee stated that the Calculated Panel Reactive Antibody (CPRA) would effectively minimize positive crossmatches as long as every candidate enters all of its unacceptable antigens. This includes those antigens that are not explicitly required by OPTN/UNOS policy (e.g. DP). This exhaustive antigen analysis would also need to be performed on donors. Representatives from the Histocompatibility Committee indicated that the additional analysis should not be too burdensome as these tests are not uncommon and would only need to be performed on those donors where a potential candidate has sensitivities to an antigen not currently required by OPTN/UNOS policy.

Past simulation modeling had evaluated regional sharing considering all possible donors. Considering the current pediatric preference for donors under the age of 35, call participants requested additional simulation of regional sharing only for those donors under the age of 35.

A draft of this concept as it has been discussed to this point is being prepared. This will be used to help recognize other details and questions that need to be addressed in further discussions. Further discussions will entail reaching out to the OPO Committee for its insights. There is also a desire for a "virtual trial" of this concept to accumulate some additional data prior to its use for kidney allocation.

A Committee member questioned if there had been discussions about what to do with the donor kidney in case of a positive crossmatch. This question has been raised multiple times, but additional recommendations outside of how donor kidneys are currently reallocated have not been recognized. Having the local OPO reallocate the kidney that was declined for its original, intended recipient due to a positive crossmatch may be the best reallocation method; however, this question will continue to be considered.

Examination of Pediatric Preemptive Listings with a GFR Value at Listing of Over 30 mL/min/1.73 m<sup>2</sup>- The Kidney Working Group met by teleconference in February to discuss the implications of establishing a minimum glomerular filtration rate (GFR) for pediatric kidney candidates to begin accruing waiting time. At its September 2011 meeting, UNOS Research Support Staff to the Committee, Wida Cherikh, Ph.D, presented an analysis requested during that call that evaluated pediatric preemptive listings with a GFR greater than 30 mL/min/1.73 m<sup>2</sup> at the time of listing. The analysis evaluated all candidates who were under age 18 at the time of listing

during 2006-2007, and GFR was calculated using the Schwartz Formula. To summarize the results:

- The percentage of preemptive listings with a GFR value over 30 mL/min/1.73 m<sup>2</sup> was 23.2% for ages 14-17, but it was as high as 17.9% for ages 6-10 and 14% for ages 0-5.
- The percentage of preemptive listings with a GFR value over 30 mL/min/1.73 m<sup>2</sup> for 14-17 year olds was highest for age 14 at 28.9%, then 23.4% for age 17, 20.9% for age 15, and 20% for age 16.
- Listing candidates with a GFR value over 30 mL/min/1.73 m<sup>2</sup> seemed to occur for all pediatric age groups and not solely those pediatric candidates aged 17.
- Due to small numbers and high variability of reported diagnoses, it was difficult to assess from the data why certain diagnoses were listed preemptively with a GFR value over 30 mL/min/1.73 m<sup>2</sup>.
- Among the pediatric candidates preemptively listed with a GFR value over 30 mL/min/1.73 m<sup>2</sup> in inactive status, the most common diagnosis categories were congenital, rare familial, and metabolic diseases (27%), tubular and interstitial diseases (27%), and glomerular diseases (24%).

As preemptive listings with a GFR over 30 mL/min/1.73 m<sup>2</sup> is consistently seen across all age groups, and not predominately in the 17 year old population, the observation was made that this addresses the concern that centers are “gaming the system.” The Vice Chair of the Committee, Heung Bae Kim, M.D., cautioned against using the term, “gaming the system,” as current policy permits these listings. If there is concern that this listing strategy is not appropriate, then the Committee should work to modify policy. The Committee was reminded that the Kidney Committee has asked it to discuss if there would be a reasonable GFR minimum for pediatric candidates to begin accruing waiting time that could be incorporated in the new kidney allocation system that is being developed. Recent Kidney Working Group discussions have indicated that a GFR of 30 mL/min/1.73 m<sup>2</sup> would be reasonable.

Committee members questioned if the Pediatric Committee should take a more proactive approach to establishing a GFR value for pediatric kidney candidates to accrue waiting time. The Committee recognized that this concern is frequently raised, and will likely continue to be. Committee members commented that it may be prudent to address this now with criteria the Committee would be comfortable with and avoid these conversations in the future. The Vice Chair indicated support and added there would need to be some mechanism to allow unique cases with a GFR greater than 30 mL/min/1.73 m<sup>2</sup> to begin accruing waiting time. Committee members could not think of examples of a candidate that would need an isolated kidney transplant with a GFR greater than 30 mL/min/1.73 m<sup>2</sup>. Along these lines, Alan Farney, M.D., Ph.D., indicated that Medicaid in his state (North Carolina) only covers kidney transplants for pediatric candidates with a GFR of 30 mL/min/1.73 m<sup>2</sup> or less. Some Committee members still felt that there could be cases where candidates would need a kidney transplant with a GFR greater than 30 mL/min/1.73 m<sup>2</sup>, and these candidates would need to be accounted for. UNOS staff questioned if the added complexity for this process would be worthwhile considering the anticipated frequency of these cases. The Committee replied it believed establishing this process and executing it did not need to be cumbersome, and would be important to include. A motion was made to recommend to the Kidney Committee that a minimal GFR of 30 mL/min/1.73 m<sup>2</sup> be established for the initiation of waiting

time accrual for pediatric kidney candidates, and that appropriate review of unique cases where it seems a transplant is needed but the pediatric patient's GFR is greater than 30 mL/min/1.73 m<sup>2</sup> be investigated. The Committee approved this motion: 25 support, 1 oppose, 0 abstentions.

This analysis also evaluated the pediatric preemptive additions to the kidney alone waiting list with a GFR greater than 30 mL/min/1.73 m<sup>2</sup> that were inactive. Committee members commented that the most common diagnoses among those listings (pyelonephritis/reflux nephropathy-18.2%, focal glomerular sclerosis, congenital obstructive uropathy, and polycystic kidneys - each at 15.2%) are diseases that require a nephrectomy, at which time the candidate would be temporarily inactivated. The Committee stated that these data gave good insight regarding pediatric kidney candidates who are inactive on the waiting list.

*Evaluation of Modification to OPTN/UNOS Policy on Pediatric Priority for Kidneys from Deceased Donors under Age 35-* The Committee annually reviews data to evaluate the impact of Share 35. To summarize the results presented at this meeting:

- After Share 35, there has been an increase in absolute numbers of all kidney transplants in children (from 4,030 during 5 years pre-policy to 4,407 during 5 years post-policy) as well as an increase in the number of deceased donor transplants for all pediatric age groups (from 1,934 to 2,910).
- Very few children are receiving transplants from donors over the age of 34 since Share 35.
- There has been a decrease in the absolute number of living donor kidney transplants in children of all ages (from 2,096 to 1,497).
- There is an increase in the number and percent of children who are receiving more poorly matched deceased donor kidneys.
- Total time on the wait list has gone down considerably, and more patients are being transplanted preemptively.
- Overall transplant rates per 1,000 active patient years have increased for all pediatric age groups.
- There was a significant increased likelihood of transplant during the post-policy period for all blood types in the 11-17 age group, for blood types B and O in the 6-10 age group, and for blood type O in the 0-5 age group.
- There was also a significant increased likelihood of transplant during the post-policy period for the 1-20% sensitization level in the 0-5 age group and for the 1-20% and 21-79% sensitization levels in both the 6-10 and the 11-17 age groups.
- While the percentage of pediatric registrations has decreased by 6% (799 in September 2005 vs. 755 in January 2011), the percent of children listed as inactive has gone up from 28% to 52%.
- The number and percent of parents donating to their children has gone down from 1,540 (73%) during the 5-years pre-Share 35 to 1,015 (66%) during the 5-years post-Share 35.

- Serum creatinine distributions were similar between pre- and post-policy periods.
- Rates of delayed graft function and treatment for acute rejection at 6 months and 1 year post-transplant slightly decreased for pediatric recipients of both deceased and living donor transplants after Share 35.
- Despite more poorly HLA matched transplants after Share 35, unadjusted graft and patient survival within 36 months of deceased donor or living donor transplant was not adversely affected.

A Committee member suggested that the resulting efforts of the Collaborative may have indirectly attributed to the decrease in living donation. She stated the timing and decreasing trend in living donation is very similar to the increases in donor organs attributed in part to the Collaborative. Another Committee member indicated that potential living donors should be pursued for pediatric candidates if possible, and transplanted in these candidates instead of a deceased donor kidney. There was concern that providers are biasing the advantages of Share 35, as it was her opinion that greater access to deceased donor kidneys should not mitigate the long term benefits of a living donor transplant. Another Committee member commented that another factor that has yet to be evaluated is the diminishing health of the general adult population as it pertains to living donation. Data is not available to formally evaluate this, but in her own experience she commonly encounters obese or hypertensive parents that are not suitable to be considered as living donors. She continued that the increase in unrelated living donation is encouraging. Another committee member agreed that the health of the parents, along with more stringent guidelines for living donor consideration, likely plays a major role in this decreasing trend.

A new Committee member asked whether adult time to transplant after Share 35 was included in the yearly analysis. Committee members replied that adult kidney candidates' time to transplant likely has increased. This is not a function of Share 35; rather, it is because the number of available deceased donor kidneys has remained stagnant while the kidney waiting list has grown. Dr. Cherikh reminded the Committee that the report corresponding to this data presentation contains some data evaluating the number of adult transplants since Share 35, which do not suggest a significant impact. Another new committee member asked what measures were being used to gauge the success of Share 35. Committee members replied that one of the main goals of Share 35 is to decrease pediatric kidney candidates' time to transplant, and this has been observed since the implementation of Share 35.

#### 4b. Status of Thoracic Organ Allocation Policy Review

*August 29<sup>th</sup> Joint Pediatric Committee Thoracic Working Group/Thoracic Committee Heart Subcommittee Teleconference-* During the Committee's September 2011 meeting, the Committee Chair, David Campbell, M.D., updated the Committee on a recent teleconference with the Thoracic Working Group of the Committee and the Heart Subcommittee of the Thoracic Organ Transplantation Committee (Thoracic Committee). To provide some background for context, Dr. Campbell explained that the majority of pediatric heart candidates, especially infants, are listed as Status 1A. As a result, heart allocation is highly dependent upon waiting time. Accordingly, representatives from the Pediatric and Thoracic Committee have been working to redefine the criteria for the current three tier system (Status 1A, Status 1B, and Status 2).

During the August 29 discussion, committee members reviewed data compiled by the Pediatric Heart Transplant Study (PHTS). Specifically, this analysis focused on the time on extracorporeal membrane oxygenation (ECMO) data that are not collected by the OPTN. These data confirmed

call participant's assumptions that outcome results are worse the longer a candidate is on ECMO; outcomes are also poor if the candidate is on ECMO at the time of transplant.

After these data were reviewed, participants began to reorganize status criteria. This effort is a work in progress, and Committee members were reminded of three upcoming teleconferences that have been scheduled in hopes of having a proposal for consideration during the spring 2012 public comment cycle.

Currency of Policy 3.2.1.6 (Registration of In Utero Transplant Candidates) & 3.2.1.7 (In Utero Waiting Time)- At the Committee's April 2011 meeting, discussion revealed a general consensus that policies pertaining to *in utero* listings had marginal value, and stood to be deleted from policy. Committee members were hesitant to act on this immediately, and wanted to converse with their colleagues before making a formal recommendation regarding these policies. William Mahle, M.D., Thoracic Committee crossover representative, explained the rationale for these *in utero* listings and how the allocation and corresponding transplant may occur. In practice, these listings are extremely rare, and all of these candidates were born before being removed from the waiting list.

Dr. Mahle informally polled those centers that have listed a candidate as *in utero*. He indicated that a frequent response was that the center had not considered listing an *in utero* candidate for a heart transplant in years. One center did express a desire to retain the *in utero* listing option, but all others expressed no concern with a recommendation to eliminate this option, citing the frequency that this listing is used and the minimal benefit that has been realized from these listings. Dr. Campbell echoed these sentiments. Another consideration is that those tests evaluating a fetus for transplant are not as thorough as what can be done once the patient is born. It would not be uncommon for a child to be delivered for transplant (or otherwise) to then be reevaluated and recognized as not needing a heart transplant. Dr. Mahle agreed, stating that his center would not take a newborn candidate to surgery before running a number of other tests (e.g. renal and head ultrasound). Other Committee members commented that these sentiments were generally what their colleagues had indicated as well.

A motion was made that the Committee should submit for public comment the elimination of all policies allowing *in utero* listings. The Committee unanimously supported this motion (26 support, 0 oppose, 0 abstentions).

Modifications to policy 3.7.8 (ABO Typing for Heart Allocation) and 3.7.8.1 (Heart Allocation to Pediatric Candidates Eligible to Accept a Donor Heart of Any Blood Type)- UNOS implemented ABO-incompatible heart policy modifications in November of 2010. Upon implementation, a condition to be eligible for an incompatible heart transplant required the entry of isohemagglutinin titer values for all born candidates. Shortly after implementation, UNOS received a question from a member asking whether a candidate's IgG or IgM titer value should be entered. This question was posed during a Pediatric Committee Thoracic Working Group/Thoracic Committee Heart Subcommittee teleconference, and participants indicated that with respect to minimizing risk, if multiple isohemagglutinin titer values are reported, the highest titer value should be entered in UNet<sup>SM</sup>. Initially, the group thought an educational effort to make this clarification would suffice, but it was later recognized that a recommendation is not mandatory and that this clarification should be included in policy. Accordingly, this clarification is being prepared for the Executive Committee's consideration.

The Committee was informed that modified policy language had been drafted, but there were still additional edits to be incorporated by the Thoracic Committee's Vice-Chair. Upon these edits being made, this language will be distributed among the Committee for its review. At the end of this

review, the Committee will be requested to vote on these clarifications to the policy language before the Executive Committee's consideration.

*Waiting Time Accrual for Inactive Priority 1 Pediatric Lung Candidate-* UNOS staff explained that currently, lung candidates continue to accrue waiting time as Priority 1 if they were at Priority 1 at the time they were inactivated. UNOS IT staff was concerned about the consistency of this waiting time accrual, and asked the Committee to discuss if the current programming aligns with the Committee's original intent. The Committee liaison provided the Committee with the original policy language that was approved, and reminded it how the current policy language evolved from that in an effort to simplify the programming effort while retaining the Committee's intent.

Committee members initially indicated that pediatric lung candidates should not accrue waiting time at Priority 1 while they are inactive. Another Committee member asked if there was good reason for these lung candidates to be inactivated temporarily, in which case, maybe it is appropriate that they continue to accrue this waiting time. In raising this question, intestine candidates' ability to continue accruing waiting time for 30 days while inactive was alluded to. Committee members stated that there could be appropriate reasons a candidate would need to be inactivated temporarily. An infection needing management was given as an example of situation that would make the candidate temporarily unsuitable for transplant, but does not mitigate their urgent need for transplant. Committee members did not believe that candidates should accrue waiting time at Priority 1 indefinitely, but that a short period of time where a candidate continues to accrue waiting time while inactive would be appropriate.

UNOS staff also pointed out to the Committee that these Priority 1 candidates who are accruing waiting time while inactive seem to be in conflict with policy 3.7.9 (Time Waiting for Thoracic Organ Candidates), which states:

“Waiting time will not be accrued by candidates awaiting a thoracic organ transplant while they are registered on the Waiting List as inactive, except as specified in Policy 3.7.9.3 (Waiting Time Accrual for Lung Candidates Less than 12 Years of Age).”

The Committee was reminded that the exception referring to 3.7.9.3 was added when the policy language was modified to simplify the programming effort for the purposes of the Priority 2 tiebreaker, which considers the candidate's entire time on the waitlist - inactive and active time. The Committee recognized that the current programming could be seen as appropriate considering this policy does not specifically recognize Priority 2 waiting time calculation as the sole exception to 3.7.9.3.

Committee members commented that if a candidate is temporarily unsuitable for transplant, but still an urgent case, the transplant center could keep the candidate active and refuse any organ offers received during that temporary time frame, citing refusal code 801 (Candidate ill, unavailable, refused, or temporarily unsuitable). Committee members voiced concerns with using this strategy, expressing worries about potential audits of refusals for active candidates. Other Committee members believed that these refusals could be justified. Those with concerns with this approach indicated a preference to avoid those discussions completely, and continued that their center's practice would be to inactivate these urgent candidates that are temporarily unsuitable for transplant.

The variability in how different centers would handle these candidates who are temporarily unsuitable for transplant (entering refusal code 801 versus inactivating the candidate) concerned the Committee in that some candidates would not receive the same benefit (amount of waiting time) as

others. The Committee did not believe a candidate who is temporarily unsuitable for transplant should have their Priority 1 waiting time reset. The Committee communicated that it would be reasonable for these Priority 1 candidates to continue accruing active waiting time while inactivated for a short period of time- 30 days was suggested. Just as important, these candidates who are temporarily inactive but still urgently need a transplant should not have their waiting time reset. Another Committee member pointed out that it probably is appropriate for those candidates that fluctuate between Priority 1 and 2 to have their Priority 1 waiting time reset as they are likely not as urgent as a candidate who has been exclusively listed as Priority 1; however, he agreed that a brief inactive period should not reset a candidate's Priority 1 waiting time.

The Committee agreed it should recommended that Priority 1 candidates who are inactive should continue to accrue Priority 1 waiting time for 30 days, and their waiting time should not be reset upon being activated. The Committee will solicit the Thoracic Committee's feedback on this issue via a memorandum that will outline this discussion and the corresponding recommendations.

*Completeness of Diagnosis Codes for Pediatric Lung Candidates-* UNOS staff summarized the issue, reminding the Committee that pediatric lung candidates must provide certain data prior to their 12<sup>th</sup> birthday to prepare for their transition to a lung allocation score (LAS) to be prioritized for deceased donor lung offers. One data element is the candidate's diagnosis. Due in part to the dependency of a candidate's LAS on this diagnosis, "other" (with a free text field) is not an option for these candidates to select on Waitlist<sup>SM</sup>. Tiedi® forms used for reporting purposes do include "other" (with a free text field) as a diagnosis option. In an effort for the diagnosis list on Waitlist<sup>SM</sup> to be exhaustive, the Committee was asked to review those responses (that UNOS staff was unable to "reclassify" as one of the current diagnoses) that have been entered in Tiedi® for "other" diagnoses, and indicate if any should be included in the Waitlist<sup>SM</sup> diagnosis list. Additionally, the Committee was asked to provide any other diagnoses that are not included on either list, but that should be a diagnosis option.

Committee members first stated that an exhaustive list would not be absolutely complete for a long period of time; new and unique situations will always present themselves. With that understanding, the Committee focused on the list of diagnoses that were collected from the Tiedi® forms. Regarding those "other" diagnoses that indicate two or more diagnoses, Committee members said a center should only document one of these- whichever diagnosis benefits the candidate's LAS the most. The Committee opined that the majority of all the other diagnoses could be classified as one of the current, established diagnoses. It may be helpful to include some of these items on the diagnoses list provided on the Tiedi® forms, to attain more detailed information. Considering the effort required to modify the diagnoses that will be included in the LAS for allocation purposes, the Committee indicated these additional options are not necessary to incorporate in the Waitlist diagnosis list as these diagnoses could be denoted as one of the currently established LAS diagnoses. The Committee recommended the following be incorporated only on the diagnoses list for the Tiedi® forms:

- Nonspecific interstitial pneumonia (NSIP)
- Pneumoconiosis
- Chemotherapy/radiation-induced
- ABCA3 gene mutation

The Committee recognized two other diagnoses included on the "other" list that it did not think would fit well into any of the current diagnoses: pulmonary lymphangiectasia and

alveolar capillary dysplasia. These diagnoses should also be included on the Tiedi® forms; however, each of these diagnoses was only cited once, and therefore the benefit of including these in the LAS calculation may be minimal and would need to be evaluated.

The Committee indicated it could not think of any other diagnoses that are not included on either list that should be included.

*Evaluation of Policy on Broader sharing of lungs from 0-11 y.o donors/ simple priority system for 0-11 y.o lung candidates-* Dr. Cherikh presented data to help the Committee evaluate the impact of the policy changes it recommended for the broader sharing of lungs from deceased donors less than 12 years of age and the establishment of a simple priority system for 0-11 year old lung candidates. The policy changes were implemented on September 12, 2010, and the analysis evaluated deceased donor lung dispositions and deceased donor lung transplants during eight months prior to the policy's implementation (1/12/10-9/11/10) as it compared to eight months of data after the policy's implementation (9/12/10-5/11/11). To summarize the results:

- Over half of the pediatric additions during 8 months post-policy were listed in Priority 1.
- Since policy implementation, the majority of registrations waiting were listed in Priority 2.
- Across all donor age groups, there was not much change in the distribution of deceased donor lung dispositions during the 8 months post-policy as compared to the 8 month period pre-policy.
- The percentage of Zone B transplants performed in 0-11 recipients from 0-11 donors has increased since policy implementation.
- During 8 months post-policy implementation, all 13 recipients aged 0-11 received their lung alone transplants from donors 0-11 in Priority 1, and none were performed locally.

*Evaluation of Policy on Broader Sharing of Pediatric Heart Donors for Pediatric Status 1A/1B Candidates-* Dr. Cherikh next provided an analysis of another policy sponsored by the Committee that had been recently implemented- the broader sharing of hearts from pediatric deceased donors for pediatric Status 1A and 1B candidates. UNOS implemented these policies on May 6, 2009, and the analysis compared all candidates that were less than 18 at the time of listing during 17 months before and after the policy modifications were implemented (pre-policy: 12/6/07-5/5/09; post-policy: 5/6/09-10/5/10). To summarize the results:

- The majority (~69%) of pediatric candidates were added on the heart alone waiting list in Status 1A.
- There was a higher percentage of pediatric candidates aged <1 listed in Status 1A (~86%) compared to candidates aged 1-10 (59%) and candidates aged 11-17 (58%).
- There was no change in the distribution of candidates added to the heart alone waiting list by medical urgency status during pre- and post-policy periods.
- Among pediatric and adult heart candidates, there seemed to be a decrease in Status 1A and Status 1B waiting list death rate during 17 months after the

broader sharing of pediatric hearts policy was implemented, although transplant rate did not seem to change.

- Among pediatric candidates <1 at listing, transplant rate in Status 2 increased, and overall transplant rate increased for this group of candidates.
- During post-policy period, there was no increase in the number and percent of hearts that were transplanted from pediatric or adult donors.
- There was an increase in the number and percent of Status 1A combined local and Zone A pediatric transplants from pediatric donors during 17 months after policy implementation.
- Although there was an increase in the number and percent of Status 1B combined local and Zone A pediatric transplants from pediatric donors during 17 months after policy implementation, the percent did not increase.

*Evaluation of ABO-Incompatible Heart Policy-* Continuing the evaluation of recently implemented policies, Dr. Cherikh presented an analysis of the preliminary impact of policy changes that modified the criteria to qualify for an ABO-incompatible heart offer. These policies were implemented on November 22, 2010. To summarize the results of this analysis:

- Only 32% of the 100 non-AB registrations added to the heart alone waiting list before the age of 2 and in Status 1A or 1B at listing indicated a willingness to accept a heart from an incompatible blood type at listing, most of whom were less than 1 year at time of listing.
- None of the candidates listed between the ages of 1 and less than 2 indicated a willingness to accept an ABO-incompatible heart at listing.
- Of the registrations still waiting on July 31, 2011, 29% were willing to accept a heart from an incompatible blood type.
- All 7 ABO-incompatible heart transplants during 11/22/10-5/31/11 were performed in recipients less than a year old at both listing and transplant.

A question was raised about what it meant to indicate a willingness to accept an ABO-incompatible heart transplant. Staff responded that indicating a willingness to accept an ABO-incompatible heart transplant was only one step in qualifying for these heart offers. Candidates also had to meet the other requirements outlined in policy, meaning that a candidate could indicate a willingness to accept an ABO-incompatible heart transplant but not necessarily be eligible. The Committee cautioned against drawing too many conclusions from the number of candidates who indicated a willingness to accept an ABO-incompatible heart transplant, as many centers likely would not enter this information knowing that the candidate's isohemagglutinin titer values are too high to qualify. Committee members suspected that if a pediatric heart candidate's willingness to accept an ABO-incompatible heart offer were a required field for all heart candidates waitlisted before their second birthday, these results would be quite different.

Other Committee members expressed disappointment that candidates between ages one and two had not utilized this policy yet. This could indicate that these candidates are receiving appropriate access to ABO-compatible heart offers; however, Committee members felt it was more likely a reflection of low isohemagglutinin titer thresholds being set for these candidates to be eligible. Committee members alluded to published literature

indicating that these transplants could be safely performed in candidates with higher isohemagglutinin titer values. UNOS staff reminded the Committee that these policies were drafted early in the study of ABO-incompatible heart transplants. As such, the transplant community implored the Committee to err on the side of caution. As the Committee continues to evaluate the impact of these policy changes, expanding these criteria needs to be considered. This should include less conservative isohemagglutinin titer values, as well as prioritizing these candidates within the current ABO-compatible heart allocation classifications. Committee members indicated that the literature also reports equivalent outcomes for those candidates that are deemed suitable, and ultimately transplanted with ABO-incompatible hearts (currently ABO-incompatible potential transplant recipients fall near the end of a heart match).

*Evaluation of New Pediatric Specific Data Elements Added to the Thoracic Forms on 3/1/2008-* The Committee continued its ongoing review of pediatric specific data elements that had been added to data collection forms on Tiedi® in 2008. The Committee was reminded that the purpose of this review is to evaluate the quality of the responses to those pediatric specific data elements that have recently been added. Responses for these data elements were summarized for each form type, each organ type, and stratified by time period (3/1/08-9/30/09 vs. 10/1/09-4/30/11). The major findings of the analysis are:

- Across the new pediatric specific data elements added to the thoracic forms, rate of unknown response seems to have decreased during the second period (10/1/09-4/30/11) as compared to the first (3/1/08-9/30/09).
- Across the new pediatric specific data elements added to the thoracic forms, rate of unknown response appears to be slightly lower on TRRs than TCRs.

UNOS staff specifically asked the Committee to comment on the results to the question, “Any prior thoracic surgery other than previous transplant?” which an affirmative answer prompts the user to answer “yes,” “no,” or “unknown” to the following three questions: prior sternotomies? prior thoracotomies? prior congenital cardiac surgery? A small portion of respondents answered yes to the first question, and either “no” or “unknown” to the three follow-up questions. UNOS staff asked if the parent question should be deleted (as the follow-up questions are not seen until it is answered in the affirmative) or if additional thoracic surgery questions should be asked. Committee members were not alarmed by this, and indicated that additional data could be collected to fully explain these situations. These more specific questions would significantly increase the data burden and would not yield a significant amount of data for additional analysis. Ultimately, the Committee advised that these questions remain unchanged.

#### 4c. Status of Liver and Intestinal Organ Allocation Policy Review

*Split Liver Concept-* For the benefit of new Committee members, and to prepare the rest for the presentation of the Committee’s split liver concept at the upcoming UNOS regional meetings, Dr. Kim reviewed the concept- the arguments that will be made, the data that supports these arguments, and the impact that can be anticipated if these changes are adopted. Alluding to the current proposal the Liver and Intestinal Organ Transplantation Committee (the Liver Committee) has out for consideration regarding regional sharing of livers for all candidates with a MELD/PELD score higher than 35, the Committee recognized that support for it would mean that element of this concept would need to be modified. The Committee did not express any concern with this modification. It was also clarified that only candidates less than two at the time of the match run would be prioritized to receive a segmental transplant. This is to focus the increased priority on

those candidates with the highest waitlist mortality, and to avoid older candidates retaining this priority to initiate more technically challenging split liver procedures that have not proven to be as successful as the left lateral segment split transplants. A Committee member questioned if a minimal PELD threshold would be established. As indicated by the analysis presented during the Committee's April 2011 meeting investigating those pediatric candidates that are removed from the waitlist for death or being too sick, these infant candidates degrade very quickly. Therefore, there will be no minimal PELD threshold to qualify for this added priority for a segmental liver transplant.

A Committee member from Region 2 indicated that he did not believe the alternative allocation system for Region 2 that was approved to promote split liver transplantation had much of an impact thus far. He opined that unless there is a strong relationship between the transplant center that has accepted the liver and its associated pediatric hospital; programs are still hesitant compromise the outcome of their index patient by removing the left lateral segment. This is especially the case when the pediatric center requests more liver vasculature than the adult program is comfortable with. To this point, the question was raised if this concept should advise on the technical aspects of the split. Committee members indicated that it felt the current policy was sufficient to this point considering that implementation of the Committee's concept will likely result in these prioritized, infant, liver candidates being the index patient.

Dr. Kim alerted the Committee that an abbreviated presentation of what was just shown will be presented at each of the upcoming regional meetings. He requested that Committee members attending these meetings be prepared to provide further detail if questions are raised. Debates regarding the merit of segmental liver transplantation are hoped to be avoided, but all feedback is welcome. A concept evaluation form was drafted to help facilitate this collection of feedback. The Committee reviewed the form that will be provided at the regional meetings, and all the feedback received will be compiled for the Committee's review.

*Waiting List Death Rates for Pediatric Liver Candidates and Characteristics of Pediatric Liver Candidates Who Died or were Too Sick on the Waiting List-* At the Committee's April 2011 meeting, the Committee reviewed an updated analysis of characteristics of pediatric candidates who were removed from the liver alone waiting list for death or too sick during 1/1/09-6/30/10. It was noted during the Pediatric Committee meeting that 41% of the 51 pediatric deaths during this period had a diagnosis of "other," and 30% of the 30 removals had a diagnosis of biliary atresia. The Committee requested a tabulation of the text field under the "other" diagnosis category for removals for death and diagnosis distribution of the pediatric candidates on the liver alone waiting list. To summarize the results:

- After re-categorizing the "other" text fields, the "other" diagnosis category for removals for death decreased from 41% (21 out of 51) to 18% (9 out of 51).
- Biliary atresia was the most common diagnosis for all additions and all removals for death, accounting for at least one-third of all diagnoses in each case.
- The percentage of candidates with "other" diagnoses was the highest among candidates removed for death, followed by additions during the same time period, and candidates removed for too sick.

*Evaluation of Liver-Intestine Allocation for Donors Aged 0-10: Waiting List Death Rates and Number of Transplants-* The Pediatric Committee was presented with an updated data analysis after the implementation of liver-intestine allocation policy for donors aged 0-10 years old implemented on 6/20/07. The updated analysis included any combined liver-

intestine transplants and registrations (with or without other organs). The following cohorts are used in the waiting list report: 8/24/05-6/19/07 and 6/20/07-10/31/10. Relative risk of death was calculated by dividing the death rate per years at risk for the candidates post liver-intestine allocation policy implementation (6/20/07-10/31/10 period) with the death rate for the reference group (8/24/05-6/19/07 period).

To summarize the results:

- Following policy implementation on 6/20/07, percent of pediatric liver-intestine additions aged 0-11 decreased and percent of adult additions increased.
- Death rates significantly decreased for pediatric candidates aged 0-11 at listing who were waiting for a liver-intestine transplant after policy change.
- Death rates also decreased for liver-intestine pediatric candidates aged 12-17, but the decrease did not reach statistical significance.
- Death rates increased for liver-intestine adult candidates, but this did not reach statistical significance.
- There was a higher percentage of 0-11 candidates who died in Status 1B or inactive status following policy implementation.
- There was a higher percentage of adult candidates who died in MELD 15-24 or inactive status after policy implementation.
- Most liver-intestine transplants in pediatric recipients were performed with MELD/PELD scores of 25+, whereas most transplants in adult recipients were performed with MELD scores of 15-24.

A Committee member commented that it is important to remember that there have been substantial changes in the way these patients are managed. He opined that these improvements captured in this data analysis are likely due more to this improved care than the policy changes.

*Evaluation of Broader Sharing of Livers/Liver-Intestines from 0-10 Year Old Donors-* On November 18, 2010, UNOS implemented a new pediatric liver/liver-intestine allocation policy involving broader sharing of livers and liver-intestines from 0-10 year old donors. Dr. Cherikh provided a preliminary analysis to help the Committee evaluate the impact of these policy changes. Deceased donor liver alone and liver-intestine (with or without other organs) transplants during 6 months pre- (5/18/10-11/17/10) and 6 months post-policy (11/18/10-5/17/11) were included. To summarize the results:

- The number of Status 1A liver alone transplants performed in 0-11 recipients from 0-10 donors increased almost 7-fold post-policy.
- Following policy implementation, the percentage of all liver alone and liver-intestine transplants in 0-11 recipients from 0-10 donors increased.
- The percentage of liver-intestine transplants performed from 0-10 donors to 0-11 recipients in Status 1B or PELD 29+ increased after policy implementation.
- Post-policy, the percentage of livers and intestines recovered and transplanted from 0-10 donors decreased, while the percentage of livers and intestines from 0-10 donors that were not recovered increased.
- The number and percentage of 0-10 and 11-17 livers discarded (recovered for transplant but not transplanted) decreased post-policy implementation.

5. Addition of Pediatric Transplantation Experience Considerations in the Bylaws

Dr. Campbell provided background of this issue for the Committee at its September 2011 meeting. He explained that, due to the current silence in the bylaws, it is possible for primary physicians and primary surgeons at hospitals that primarily serve pediatric patients to be approved for these leadership roles without any pediatric transplant experience. He stated that past Committee discussions have clearly denoted a desire to establish some basic requirements for a primary surgeons and primary physicians who work at transplant centers that predominately serve pediatric candidates. Before moving forward with these efforts, he wanted to see if the current composition of the Committee felt the same about establishing these requirements. The Committee was still in agreement that this needed to be addressed.

A Committee member indicated support for this effort, but cautioned that it will be important that “pediatric transplant experience” is demonstrated across all age groups of pediatric candidates- experience with infant transplant candidates is not the same as experience with teenaged transplant candidates. The Committee agreed, and is hopeful that these types of considerations will be feasible to incorporate in any proposed requirements. Committee members indicated that other professional groups have already established some competency requirements, and it would be important that the OPTN requirements align with these. The American Board of Pediatrics and the American Board of Internal Medicine were two examples given. The Committee agreed to review some of the competency requirements established by these professional organizations as a starting point for these discussions.

The Committee charged each individual organ-specific working group to begin discussing specific criteria to be included as experience requirements for primary physicians and primary surgeons for centers that predominately serve pediatric candidates.

OPTN/UNOS Pediatric Transplantation Meeting  
 July 20, 2011 Meeting  
 Teleconference/Live Meeting

NAME	COMMITTEE POSITION	On the Phone
David Campbell, MD	Chair	X
Heung Bae Kim, MD	Vice Chair	
Laura O'Melia, CPNP	Regional Representative	
Stephen Dunn, MD	Regional Representative	X
Alfonso Campos, MD	Regional Representative	
Jose Almeda, MD	Regional Representative	X
Debra Strichartz, RN, BA, CCTC	Regional Representative	
Andre Dick, MD, FACS	Regional Representative	X
Sharon Bartosh, MD	Regional Representative	X
Jeffrey Lowell, MD	Regional Representative	
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	
Shylah Haldeman, RN	At Large	
Clifford Chin, MD	At Large	X
Carmen Cosio, MD	At Large	X
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	X
Douglas Milbrath	At Large	X
Gary Visner, DO	At Large	
Jerry Wright, RN, CPTC	At Large	X
James Bowman, MD	HRSA	X
Monica Lin, PhD	HRSA	
Ba Lin, MS, MPH	HRSA	X
Wida Cherikh, PhD	UNOS Research	X
Chad Waller, MS	Committee Liaison	X
Cheryl Hall	UNOS Business Analyst	X
Franki Chabalewski, RN, MS	OPO Committee Liaison	X
Jeff Orlowski, MS, CPTC	behalf of OPO Committee	X
Rich Pietroski, MS, CPTC	behalf of OPO Committee	X
Sam Davis	past Committee member	X
Scott Elisofon, MD	past Committee member	X
Manuel Rodriguez-Davalos, MD	past Committee member	X

OPTN/UNOS Pediatric Transplantation Meeting  
September 27, 2011  
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	X
Debra Strichartz, RN, BA, CCTC	Regional Representative	X
Andre Dick, MD, FACS	Regional Representative	X
Sharon Bartosh, MD	Regional Representative	X
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	X
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	X
Kimberly Hoagwood, PhD	At Large	X
William Mahle, MD	At Large	X
Debbi McRann, RN	At Large	X
Douglas Milbrath	At Large	X
Gary Visner, DO	At Large	X
Jerry Wright, RN, CPTC	At Large	
James Bowman, MD	HRSA	Phone
Monica Lin, PhD	HRSA	Phone
Ba Lin, MS, MPH	HRSA	Phone
Wida Cherikh, PhD	UNOS Research	X
Chad Waller, MS	Committee Liaison	X
Marissa Clark, MS	UNOS Research	Phone
Jory Parker	UNOS Business Analyst	Phone