OPTN/UNOS Pediatric Transplantation Committee
Interim Report: September 27, 2011 Meeting
Chicago, Illinois

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The following report presents the OPTN/UNOS Pediatric Transplantation Committee's deliberations and recommendations on matters considered during its September 27, 2011, meeting.

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

1a. 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- The Pediatric Transplantation Committee (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. Eileen Brewer, M.D., crossover representative to the Kidney Committee, provided background information to give some context for the call. The Committee has been evaluating the effects of Share 35, and in doing so, it was recognized that highly-sensitized pediatric kidney candidates have not seen the same magnitude of benefit from these policy changes. Accordingly, the Committee has been working to improve these candidates' access. Using kidney allocation simulations, the Committee felt regional sharing of kidneys for these candidates could be a possible solution. The August 19th teleconference continued to explore the possibilities of a trial, regional allocation system for highly sensitized pediatric kidney candidates.

During the August 19th call, participants reviewed data showing the distribution of highly-sensitized candidates who are currently on the waiting list among the different OPTN/UNOS regions. There is some variation in the distribution, but the total numbers are relatively small. This led call participants to conclude that the current 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, as minimizing these occurrences will be crucial to the success of this trial. 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 their 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 by Organ Procurement Organizations (OPOs) 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 required by 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. Only using donors less than 35 for this trial would likely receive more support because of the current Share 35 priority.

A draft of this concept as it has been discussed to this point is being compiled. This will be used to help recognize other details and questions that need to be addressed. Future discussion 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 using it 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^2- The Kidney Working Group had a teleconference in February to discuss the implications of establishing a minimum glomerular filtration rate (GFR) for pediatric kidney candidates to begin accruing waiting time. UNOS Research Support Staff to the Committee, Wida Cherikh, Ph.D., presented an analysis of pediatric preemptive listings with a GFR at listing over 30 mL/min/1.73 m^2 that was requested during that call. The analysis evaluated all candidates who were less than 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^2 was 23.2% for ages 14-17, but it was as high at 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^2 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^2 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^2.
- Among the pediatric candidates preemptively listed with a GFR value over 30 mL/min/1.73 m^2 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^2 are 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 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. Along these lines, the Committee was reminded that 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^2 would be reasonable. A Committee member questioned if it would be necessary to define in policy how GFR is measured for pediatric candidates- Schwartz formula or modified Schwartz formula? Committee members commented that current policy does not

mandate how GFR should be calculated for adults or pediatrics, and that it should remain silent on this issue.

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. To avoid these conversations in the future, Committee members commented that it may be prudent to address this now with criteria the Committee would be content with. The Vice Chair indicated support and added that there would need to be some mechanism to allow unique cases with a GFR greater than 30 mL/min/1.73 m^2 to begin accruing waiting time. Committee members could not think of examples of a candidate who would need an isolated kidney transplant with a GFR greater than 30 mL/min/1.73 m^2. 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^2 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^2, and these candidates would need to be accounted for. The Committee believed that these cases would be infrequent; therefore, the additional burden to execute this should be minimal, it would just need to be determined who would review these cases. UNOS staff questioned if the added complexity for this process would be worthwhile considering the anticipated frequency. 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^2 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^2 be investigated. The Committee approved this motion: 25 support, 1 oppose, 0 abstentions.

This analysis also evaluated the preemptive pediatric additions to the kidney alone waiting list that were inactive and had a GFR greater than 30 mL/min/1.73 m^2. 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 felt these data helped explain the population of 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 deceased donor kidneys. 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. The data to formally evaluate this are not readily available, but based on her experience, she commonly encounters parents that are not suitable for living donation considerations. 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. She commented that it used to be her opinion that the availability of deceased donor kidneys was driving this trend, but considering the frequency her center declines kidneys she now believes it has more to do with the health of those who would typically be pursued for a living donor kidney.

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 does evaluate the number of adult transplants since Share 35, and the policy changes do not seem to have resulted in a major 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, which has been observed since the implementation of Share 35.

1b. Status of Thoracic Organ Allocation Policy Review

August 29th Joint Pediatric Committee Thoracic Working Group/Thoracic Committee Heart Subcommittee Teleconference- 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, and not urgency. 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 29th discussion, committee members reviewed data compiled by the Pediatric Heart Transplant Study (PHTS). Specifically, this analysis focused on 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 the 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 the thoracic polices 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 to delete policies that permit an *in utero* listing. 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 benefit that has been realized from these listings. Dr. Campbell echoed these sentiments, and based on his experience, he didn't believe the benefit of listing an *in utero* heart candidate justified the added complexity resulting from these policies, especially since this listing is infrequently used. Another consideration is that those tests evaluating a fetus for transplant are not as thorough as what can be done once the candidate 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 to eliminate the thoracic policies allowing *in utero* listings, and the corresponding listing option in UNet℠. 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 Staff provided background regarding this issue. UNOS implemented modified ABO-incompatible heart policy 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 to participants on a Pediatric Committeee Thoracic Working Group/Thoracic Committee Heart Subcommittee teleconference, and the group indicated that with respect to minimizing risk, if multiple isohemagglutinin titer values are reported, the highest titer value should be entered in UNet℠. Initially, the group thought an educational effort to make this clarification would suffice, but it was later realized that a recommendation is not mandatory and that this clarification should be included in policy. Accordingly, this is being prepared for the Board of Director'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 they are presented to the Board of Directors.

Waiting Time Accrual for Inactive Priority 1 Pediatric Lung Candidate- UNOS staff explained that lung candidates currently continue to accrue Priority 1waiting time while they are inactive if they were 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 consider if the current programming aligns with the Committee's original intent. The Committee liaison provided the Committee with the original policy language that was originally approved by the Board of Directors in June 2008. The Committee was reminded how the current policy language evolved from this to simplify the programming effort while retaining the Committee's intent.

A Committee member asked if there was good reason for these lung candidates to be temporarily inactivated, in which case, maybe it is appropriate that they continue to accrue this waiting time. An example was given of an infection needing to be managed that would make the candidate temporarily unsuitable for transplant, but does not mitigate their urgent need for transplant. In raising this question, intestine candidates' ability to continue accruing waiting time for 30 days while inactive was alluded to. Other Committee members agreed that there could be appropriate reasons a candidate would need to be inactivated temporarily. These 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 using 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 concerned with this approach indicated a preference to avoid those discussions completely and stated their center's practice would be to temporarily inactivate these urgent candidates who are temporarily unsuitable for transplant. Committee members also observed and questioned why thoracic policy does not allow active time to accrue while inactive, but it is allowed for other organ groups. Without a specific explanation why this should be the case, Committee members stated that consistency across all policies with regard to a candidate's waiting time accrual while inactive would be ideal. 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 that some candidate's would not receive the same benefit 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 who 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 initiate a candidate's Priority 1 waiting time to reset.

The Committee agreed it should recommended that Priority 1 candidates who are inactivated 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 12th birthday to prepare for their transition to a lung allocation score (LAS) to prioritize deceased donor lung offers. One data element is the candidate's diagnosis so that they may be appropriately categorized for LAS calculation. 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℠. Tiedi® forms used for reporting purposes do include "other" (with a free text field) as a diagnosis option. In an effort to make the diagnosis list on Waitlist℠ as exhaustive as possible, 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℠ 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.

The Committee 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 multiple diagnoses, the Committee recommended that 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 that is required to modify the diagnoses that will be included in the LAS for allocation purposes, the Committee did not believe these additional options were necessary to incorporate in the Waitlist diagnosis list as these diagnoses *could* be denoted under 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 did recognize 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. 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.

To conclude this discussion, 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. The analysis compared all candidates who were less than 18 at the time of listing during the 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 drawing too many conclusions from the number of candidates who indicated a willingness to accept and 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 isohemagglutinin titer thresholds being set too low 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 alluded to literature that reports equivalent outcomes for those candidates who are deemed suitable, and ultimately transplanted with, ABO-incompatible hearts.

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 to data collection forms. 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 of those elements added to the thoracic forms are as follows:

- 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 few 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.

That being said, 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.

1c. 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 public comment 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 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 who are removed from the waitlist for being too sick or death, 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 providing. 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 (due to time constraints) 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. The Committee reviewed the form that will be provided at the regional meetings. 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.

A comment was raised if there were certain diagnoses that presented extra risk than what would be expected. That is to say, it would be expected that biliary atresia would be the most commonly cited diagnosis at time of removal as it is the most common diagnosis cited when candidates are added to the waitlist. It would provide better insight if the removal diagnoses could be evaluated relative to the listing diagnosis, looking for removal diagnoses that do not align with listing diagnoses trends. Dr. Kim reminded the Committee that these data were originally requested because the percentage that cited "other" was so high, and the Committee was curious what "other" diagnoses were documented.

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, the percent of pediatric liver-intestine additions aged 0-11 decreased and the 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 in looking at these improvements in waitlist deaths 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 the 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.

2. Addition of Pediatric Transplantation Experience Considerations in the Bylaws

Develop Questions and a Framework for Discussion for Working Groups to Begin Addressing This Effort- Dr. Campbell provided some background of this issue for the Committee. He explained that, due to 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 that work at transplant centers predominately serving 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 criteria along these lines. 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 look at some of the competency requirements established by these professional organizations as a starting point for these discussions.

A Committee member indicated that intestine programs should also be addressed. Another Committee member pointed out that there are more pediatric intestine transplants done than pediatric lung transplants. Committee members responded that it may be challenging to establish these criteria for those that predominantly focus on pediatric transplants, when there are no criteria at all currently. The Committee's Liver Committee crossover representative, Simon Horslen, MB, ChB, stated that the Liver Committee is currently working on these experience requirements for intestine programs and felt that additional pediatric recommendations should be done in unison with that effort.

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
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
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Wida Cherikh, PhD	UNOS Research	X
Chad Waller, MS	Committee Liaison	X
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