

**OPTN/UNOS Pediatric Transplantation Committee**  
**Interim Report: April 11, 2011 Meeting**  
**Chicago, Illinois**

**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 April 11, 2011, meeting.*

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

1a. Liver and Intestinal Organ Allocation Policy Review

*Split Liver Allocation Modification* The Pediatric Transplantation Committee (the Committee) received an update on recent split liver allocation modification discussions had during a February 2011 joint-Pediatric/ Liver and Intestinal Organ Transplantation (Liver Committee) Working Group teleconference and March 2011 Liver Committee meeting. These discussions focused on the split liver allocation concept the Committee has been developing whereby a specified set of pediatric candidates (infants) would receive an increased priority to livers from deceased donors aged 18-34. These pediatric patients receiving increased priority would be allocated the liver with the expectation that they are transplanted with the left lateral segment of that deceased donor liver, allowing the remaining portion to be allocated following the same match run. The February 2<sup>nd</sup> joint-Pediatric/Liver Committee Working Group teleconference addressed feedback given by the Liver Committee during its review of this general idea at its October 2010 meeting; the March 23<sup>rd</sup> discussion centered on a modified iteration of the concept based on previous comments. At the end of the Liver Committee's March 23<sup>rd</sup> discussion, a motion was approved (8-support, 6-oppose, 3-abstain) to support the modified concept as it was proposed.

UNOS staff reminded the Committee that consensus building would be important in moving this proposal forward. Past Committee discussions had highlighted a need to give the community some insight into this concept prior to its submission for public comment. These discussions indicated that Committee members familiar with the concept should present this idea at regional meetings to avoid concerns resulting from any preconceived notions or an incomplete understanding of the concept, while also allowing an opportunity for interested parties to ask questions and receive informed responses.

UNOS staff reviewed data analyses requested during the October 2010 Liver Committee and February 2011 joint-Pediatric/Liver Committee Working Group discussions. The resulting data were used to develop the most recent iteration of the split liver allocation concept that was presented before the Liver Committee in March 2011. The first analysis investigated the number of segments transplanted relative to the number of segments recovered, irrespective of whether the donor met the recommended criteria for splitting, stratified by donor age; the MELD score of adult recipients of a split liver when the other segment was transplanted into a pediatric candidate; and, determined the age distribution of the recipients of the right lobe when the index patient was a child (i.e., the first candidate on the match who accepted the liver was less than 18). To summarize, the following observations were made:

- There is a slight increase in the number and percent of two segments being transplanted from two recovered segments after the split liver policy was implemented.
- The majority of the adult recipients of splits where the other segment went to a pediatric recipient had a MELD score of 15-28 at transplant.

- The majority of the second recipients of splits where the index recipients were pediatrics were adults aged 45+.

Analyzing these data, Committee members commented that it proves adult potential transplant recipients are accepting and being transplanted with split liver grafts. This indicates left lateral segment splits do not result in wastage of the other liver segment, and allow two candidates to be transplanted and removed from the liver waiting list. The Committee suggested that many of those livers that were intended to be split but only yielded one transplant likely resulted from pediatric donors where it was later realized that the liver’s physical size was too small to be split.

The necessity for increased pediatric priority and access is commonly questioned when discussing modifications to split liver allocation. UNOS staff presented a second data analysis focusing on this, and originating from the February 2011 joint-Pediatric/Liver Committee Working Group discussion. Specifically, the Working Group requested a current analysis of waiting list death rates for pediatric candidates waiting for an isolated liver, stratified by region and age group (<1, 1-5, 6-11, 12-17), and a description of characteristics of pediatric candidates who died or were removed for being too sick on the liver waiting list. Figure 1 illustrates the results from the first part of the request, clearly indicating that pediatric liver candidates less than one year of age have the highest waitlist mortality. (Candidates on the liver alone waiting list during 1/1/07-6/30/10 were included in the analysis.)

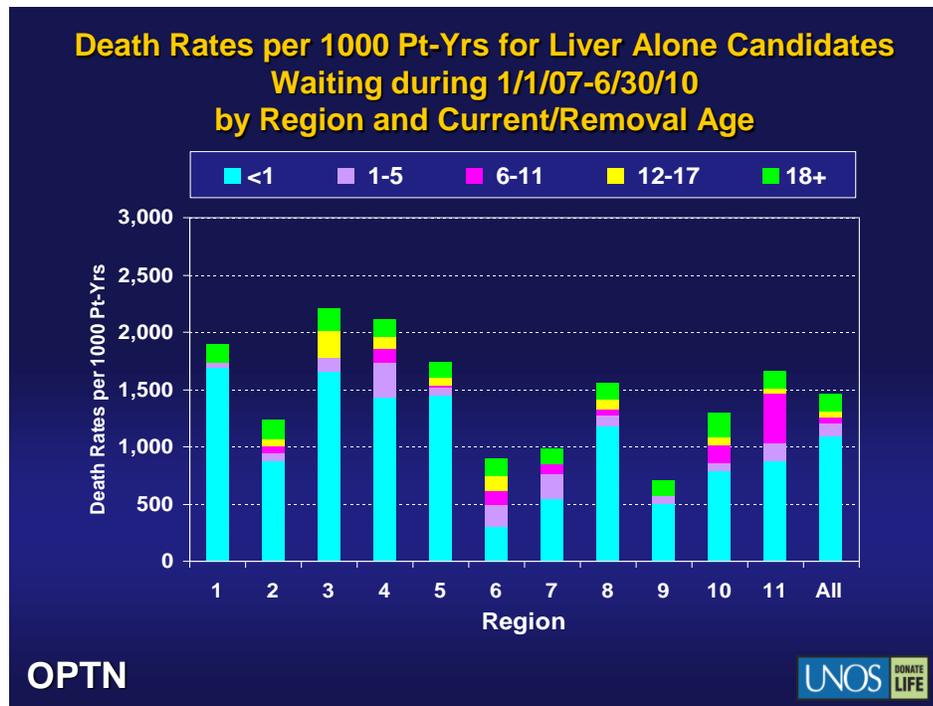


Figure 1: Death rates per 1000 patient-years for liver alone candidates waiting during 1/1/07-6/30/10 by region and current/removal age.

The second part of the data request looked a numerous elements to describe those candidates who were removed from the waiting list for death or being too sick for transplant. The following, and Table 1, summarize those data describing pediatric liver candidates who died on the waiting list:

- 73% of these candidates were awaiting their first transplant
- Median total days on the waiting list: 26 (range: 0 - 4,163)

- Median active days on the waiting list: 17 (range: 0 - 697)
- Of those who received offers, the number of offers ranged from 1 to 45
- 18 patients with >0 active days on the waiting list never received any offers; 15 of those were active for 60 days or less, the remaining 3 were active between 81-697 days
- The most common diagnosis category for these candidates was “other” (41%), followed by biliary atresia (29%), and acute hepatic necrosis (12%).
- Analyzing the initial MELD/PELD score as compared to the score at the time of removal, there is a trend that removal MELD/PELD scores tend to be higher than the MELD/PELD scores at the time of listing.

**Age at Listing and Age at Removal of Pediatric Candidates who Died on the WL during 1/1/09-6/30/10 (N=51)**

Age at Listing	Age at Removal					Total
	<1	1-5	6-10	11-17	18+	
<1	19	3	0	0	0	22
1-5	0	8	1	1	0	10
6-10	0	0	6	0	0	6
11-17	0	0	0	11	2	13
<b>Total</b>	<b>19</b>	<b>11</b>	<b>7</b>	<b>12</b>	<b>2</b>	<b>51</b>

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*Table 1: Age at listing by age at removal of pediatric candidates who died on the waiting list 1/1/09-6/30/10. (N=51)*

The following, and Table 2, summarize some of those data describing pediatric liver candidates who were removed from the waiting list for being too sick:

- 93% of these candidates were waiting for their first transplant
- Median total days on the waiting list: 12 (range: 1 - 709)
- Median active days on the waiting list: 12 (range: 1 - 539)
- Of those who received offers, number of offers ranged from 1 to 29
- 11 patients with >0 active days on the waiting list never received any offers; 10 of those were active for 30 days or less, and 1 was active for 68 days
- The most common diagnosis category for these candidates was acute hepatic necrosis (37%), followed by biliary atresia (30%), and metabolic disease and malignant neoplasms (both at 10%).
- Similar to those candidates who died on the waiting list, there is a trend that MELD/PELD scores at the time of removal for being too sick tend to be higher than the MELD/PELD scores at the time of listing.

**Age at Listing by Age at Removal of Pediatric Candidates who Were Removed from Being Too Sick on the WL during 1/1/09-6/30/10 (N=30)**

Age at Listing	Age at Removal					Total
	<1	1-5	6-10	11-17	18+	
<1	16	0	0	0	0	16
1-5	0	7	0	0	0	7
6-10	0	0	4	0	0	4
11-17	0	0	0	3	0	3
<b>Total</b>	<b>16</b>	<b>7</b>	<b>4</b>	<b>3</b>	<b>0</b>	<b>30</b>

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*Table 2: Age at listing by age at removal of pediatric candidates who cited “too sick” when removed from the waitlist 1/1/09-6/30/10. (N=30)*

Analyzing the diagnosis categories, 41% of pediatric patients who died on the liver waiting list cited “other.” A Committee member commented that it would be helpful to know what additional diagnosis information was entered for these candidates citing “other,” stating that it is hard to understand so many cases that fall outside the standard diagnosis categories. UNOS staff replied that this information could be gathered for further review. Another committee member asked if it would be possible to analyze the waitlist diagnosis categories at the time of removal relative to the waitlist diagnosis categories of the entire liver waiting list. That is to say, it is interesting to note that 29% of those pediatric liver candidates who died while on the waiting list were in the biliary atresia diagnosis group; but, this information may not be as meaningful if 85% (or some other random, high percentage) of pediatric candidates on the liver waiting list cite biliary atresia as their primary diagnosis. UNOS staff indicated that this information could be compiled for additional analysis.

The Committee commented that the trend suggesting that MELD/PELD scores at the time of removal tend to be higher than those scores at the time of listing indicates that a child with a low MELD/PELD score still faces a significant risk of death on the waiting list. These data are important in addressing concerns expressed by the Liver Committee that the split liver concept could result in infants being transplanted with a significantly lower MELD/PELD score as compared to the remainder of candidates on the match run. Committee members also commented that the brief time period from being waitlisted to being removed from the waitlist, as illustrated by the median days on the waiting list, show a need for a larger pool of donors to improve these candidates chance at getting transplanted.

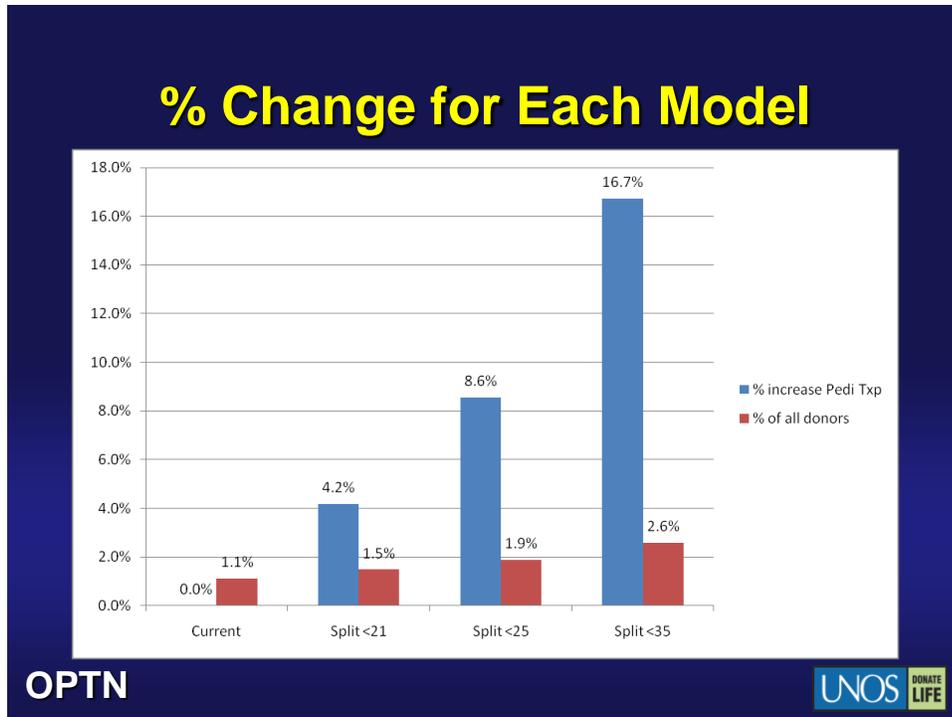
Following these data presentations, Heung Bae Kim, M.D., Committee Vice Chair and Liver Committee crossover representative, reviewed the modified split liver allocation concept that he

presented for the Liver Committee at its March 2011 meeting. The most recent iteration of the split liver allocation modification concept recommends that livers from deceased donors aged 18-34 are first offered to all Status 1A candidates in the region, then all Status 1B candidates in the region, and then all those candidates in the region with a MELD/PELD score of 30 or greater. If the liver is not accepted by any of these candidates, it would then be allocated to pediatric candidates less than the age of two that would be willing to accept a left lateral segment, allowing the remaining portion of the liver to be allocated using the same match run. If an infant potential transplant recipient accepts the left lateral segment, the remaining portion would be allocated starting with the first candidate prioritized after those in this less than two, left lateral segment classification. Modifications yielding this iteration of the concept specifically considered the elevated death rates on the waiting list for infant liver candidates as well those adults listed as Status 1A and a MELD score of 30 or greater; the desire to transplant these adult candidates with a high quality liver; and, acknowledging the higher relative risk associated with split liver grafts that is reported in the literature.<sup>1</sup>

Committee members commented that there is some relative risk when using a split liver graft to transplant an adult, but in practice did not agree with the literature's conclusion that a split liver graft has approximately the same amount of risk as a DCD donor liver. The Committee felt that this relative risk would likely decrease if this analysis were performed with an updated cohort (data are approximately 10 years old now), especially considering the implementation of MELD/PELD since this analysis. A question was raised about the power of the statistics to calculate the split liver relative risk considering the small volume of these types of transplants performed from 1998-2002. Other Committee members commented that certain single-center studies have demonstrated considerably better outcomes. The Committee opined that this reported relative risk could be seen as a worst case scenario. To that point, another Committee member cautioned making national policy based solely on the outcomes and experience of those on the Committee. A national policy will increase the possibility for all centers to perform these types of transplants, and therefore increases the likelihood of less experienced centers splitting livers and transplanting liver segments. The potential outcomes resulting from these situations must also be considered. Dr. Kim agreed with this notion, and continued to use the conclusions from this well-known manuscript to prove the merit of the current split liver allocation modification concept. Using these and OPTN data, some basic calculations were performed to investigate the potential impact of such a policy change. Assuming that donors aged 16-17 have livers that, when compared to adults, are comparable in size and suitability to be split, the percentage of those donor livers that were split was compared to the percentage of split livers from adults donors aged 18-34, and all liver transplants. The data show 6.7% of 16-17 deceased donor livers are split, as compared to 1.5% for those livers from 18-34 year olds, and 1.1% of all deceased donor livers. The difference in the frequency of split livers is attributed to pediatric candidates acting as index patients and initiating the split as a function of the allocation priority given to pediatric candidates for pediatric, deceased donor livers. This 6.7% split rate was then applied to the total number of donors who could be expected (based on donor data from 2008) if the proposed pediatric priority was implemented for deceased donors than 21, less than 25, and less than 35 years of age. The percent of change was calculated for each donor age, and the corresponding results can be seen in Figure 2.

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<sup>1</sup> Feng S, Goodrich NP, Bragg-Gresham JL et al. Characteristics associated with liver graft failure: The concept of a donor risk index. *Am J Transplant* 2006; 6: 783-790.



*Figure 2: Theoretical percentage increase of the number of livers split when the 6.4% split rate is applied to the number of donors under the age of 21, 25, and 35, respectively.*

Committee members asked if this would result in enough donors to eliminate, or at least decrease, pediatric liver waiting list mortality. Dr. Kim responded that this would likely impact the waiting list mortality, but that timing is still a major factor. A donor has to be available when the sick child is in need, and increasing the donor pool increases the likelihood of this being the case. Another Committee member pointed out that MELD/PELD scores in the region would also affect the impact of these changes. Regions with more candidates at MELD/PELD scores higher than 30 will not likely see as much an impact from this potential policy change, as those ideal livers for splitting would likely be allocated as a whole grafts prior to being offered to these pediatric candidates who would accept the left lateral segment.

Another important conclusion to deduce from Figure 2 is that this potential policy proposal will only impact approximately 2.6% of deceased liver donors, at most. The Committee anticipates that the overwhelming majority of deceased donor livers from donors aged 18-34 would still be allocated as whole liver grafts.

To have a more recent perspective on the potential risk faced by adults transplanted with a split graft, the Committee requested that an updated cohort be used to calculate those donor risk indexes (DRI) that are the basis for some of the support for this concept.

The Committee discussed possible strategies for moving forward with this concept. Questions were raised about data resulting from the split liver alternative allocation systems (AAS) that were approved at the November 2010 Board of Directors meeting. Committee members from those regions participating in the split liver AASs stated they were not aware of any preliminary results, but felt that the Committee's concept has the potential for a broader impact. The Committee's Region 2 representative indicated that the AAS was initially pursued as a means to quickly

implement some change to improve split liver allocation. He continued that due to its potential impact, he felt this concept would likely be supported as well. Committee members were reminded that these split liver AASs could still be executed as drafted if the split liver concept being developed is ultimately approved.

The Committee readdressed consensus building, recognizing its importance in this proposal's success. Regional meetings were seen as an avenue to broadcast the concept while developing the remaining details for a formal public comment proposal. A Committee member questioned if it is fair to expect those "non-liver" regional representatives to fully present the concept. This will need to be gauged in preparation for the fall regional meetings. The OPO Committee was specifically mentioned as a group that should be consulted in the consensus building effort.

Questions were raised about the actual splitting process, acknowledging different transplant programs are more comfortable with different procedures. It was noted that this would likely be raised and discussed further at regional meetings. The Committee opined that this proposal should not modify current policy regarding the process for dividing the liver graft.

A motion was made to continue developing this concept, with the intent to present the general ideas at the fall regional meetings and to continue working with the joint-Pediatric/Liver Committee Working Group to develop the remaining details of the proposal. The Committee unanimously voted to support this motion (20 support, 0 oppose, 0 abstain).

Public Comment Feedback: Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B, and Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or 1B  
Committee members briefly discussed responses to the two public comment proposals sponsored by the Committee that are currently out for consideration. Regional representatives confirmed that the proposals have received significant support at the regional meetings, and no unexpected or concerning questions were reported.

Evaluation of Liver Allocation Policies On Regional Sharing of Pediatric Donors; and Liver-Intestine Allocation for Donors Aged 0-10: Waiting List Death Rates and Number of Transplants  
UNOS staff presented a data report analyzing the impact of implemented pediatric liver policies. The following policies were analyzed: liver MELD/PELD (M/P) Share 15 policy (implemented on 1/12/05), the liver policy changes involving the refinement of Status 1 definitions into 1A and 1B, the regional sharing of pediatric liver (implemented on 8/24/05), and the liver-intestine allocation for donors aged 0 to 10 years (implemented on 6/20/07).

To summarize the waiting list data:

- There was no significant increase of death rates in pediatric candidates waiting for liver with or without exceptions across the different periods.
- Risk of death for the 0-11 candidates waiting for liver and were ever in any exceptions was significantly lower during the post policy period (6/20/07-10/31/10).
- Multiple organ system failure was the most common cause of death for liver candidates with or without exceptions.

To summarize the transplant data:

- The percent of deceased donor liver alone transplants done in PELD 15+ for 0-11 recipients seemed to slightly increase, while percent of transplants done in PELD <15 seemed to decrease in most recent period.

- There seems to be an increase in the number of deceased donor pediatric liver alone transplants from pediatric donors during most recent period.
- Most livers from 0-10 donors went to 0-11 recipients, whereas most livers from 11-17 donors went to adult recipients during both periods.
- There did not seem to be any change in the number of split liver transplants done in pediatric recipients.

Evaluation of New Pediatric Specific Data Elements Added to the Liver and Intestine Forms on 3/1/2008 UNOS staff also presented an analysis of those pediatric-specific data elements that were added to the liver and intestine data collection forms on March 1, 2008. To summarize the results:

- Across the new pediatric specific elements added to the liver and intestines forms, rate of unknown response seems to be higher for transplant recipient follow-up forms, as compared to transplant candidate and transplant recipient registration forms.
- Across the new pediatric specific elements added to the liver and intestines forms, rate of unknown response has decreased during the second period (6/1/09-9/30/10), compared to the first period analyzed (3/1/08-5/31/09).
- Rate of unknown total bilirubin is higher for death follow-up compared to annual follow-up records where recipients were reported as alive and with a functioning graft and compared to graft failure where there were no unknown responses.

A new committee member asked the purpose of reviewing these data elements. The Committee was reminded that reviewing newly implemented data elements is a regular process to assure that what is being collected is relevant and useful information. When it is time to review all the data elements for Office of Management and Budget approval, recommendations will be made to remove those elements that are determined to be not useful.

#### 1b. Kidney Allocation Policy Review

Eileen Brewer, MD, Kidney Transplantation Committee (Kidney Committee) crossover representative, updated the Committee on the current developments on the new kidney allocation system. The Kidney Committee has requested the Committee reassess the current absence of criteria to initiate waiting time for pediatric kidney candidates. Additionally, the Kidney Committee has also asked the Committee to review the current policy that classifies all candidates listed before their 18<sup>th</sup> birthday as a pediatric, even after their 18<sup>th</sup> birthday. This results in those candidates being prioritized for those donors less than 35 years of age (Share 35). The Committee's Working Group discussed this at its February 3<sup>rd</sup> conference call, and requested some data to evaluate these concerns. The Kidney Working Group felt it was well accepted and understood that a patient on dialysis should be accruing waiting time, and focused on the estimated creatinine clearances for those kidney candidates who are preemptively transplanted before dialysis. The standard Schwartz formula for pediatrics was used to estimate glomeruli filtration rate (GFR) as there is some question about the modified-Schwartz formula's applicability to adolescent patients, which are the primary group to be evaluated in this analysis. The Kidney Working Group also requested data to investigate the possibility of sharing kidneys regionally for highly-sensitized pediatric candidates.

Examination of GFR Values at Listing and Transplant by Dialysis Status, Candidate Status on the Kidney Waiting List by Age, and Distribution of Waiting List Candidates and Transplant Recipients by Region and Ethnicity UNOS staff presented the results of the following data requests made during the Kidney Working Group's February 3<sup>rd</sup> conference call:

- Calculations of GFR values at time of listing using the Schwartz formula for pediatric candidates waiting for kidney alone transplants.

- Calculations of GFR values at transplant using the Schwartz formula for pediatric recipients of pre-emptive kidney alone transplants.
- Number of inactive pediatric candidates on the kidney alone waiting list by age group at listing (to include age 16-17).
- Number of pediatric candidates waiting for kidney alone transplants and number of pediatric kidney alone transplants by region and ethnicity.

To summarize the results:

- About one-third of pediatric candidates added to the kidney alone waiting list were not on dialysis at listing.
- Inactive listings are common at every age 0-17, with age 9 having the lowest percentage (40%).
- Close to 20% of these pre-emptive listings had a GFR value of over 30 at time of listing, but this group represented only 6% of all listings.
- Analyzing kidney alone transplant recipients who were added to the waiting list as a pediatric candidate, 18% received pre-emptive transplants.
- About 11% of the pre-emptive transplants had a GFR value of over 30 at time transplant, but this group represented only 2% of all transplants.
- Among pediatric candidates still waiting on December 31, 2010, the percent in inactive status ranged from 40% for candidates added to the waiting list at the age of 9 years to 71% for candidates added at the age of 1 year.
- There were regional and ethnic differences in the numbers of pediatric kidney candidates and transplants.

The questions that need to be addressed are whether pediatric candidates would be disadvantaged by a minimal GFR to initiate waiting time; or, if a minimal GFR is appropriate, would that indirectly result in transplant centers listing more candidates at an inactive status. The Kidney Work Group discussed these questions during its April 2011 teleconference. The Kidney Working Group absolutely does not want to disadvantage pediatric candidates' access to transplant, but appreciates the desire to have minimal criteria to begin accruing waiting time. Evaluating possible minimal GFR values to initiate pediatric waiting time, some Kidney Working Group members hypothesized that a GFR of 30 may result in candidates being listed earlier than necessary, and possibly listed as inactive, as most centers would not transplant candidates until their GFR is closer to 20. The Working Group felt that a GFR of 25 would be more suitable, allowing candidates to accrue waiting time to facilitate a preemptive transplant if appropriate. Of the 2787 kidney allocations evaluated, only 53 (1.9%) had a GFR over 30. The diagnoses of these 53 transplant recipients were unknown during the discussion. Two possible diagnoses were mentioned that would need a transplant at a higher GFR, mid-aortic syndrome and congenital nephrotic syndrome, and would likely need to be considered as exceptions to any determined GFR that will initiate the accrual of waiting time. The Committee requested that the diagnoses of these 53 transplant recipients be more thoroughly investigated. (Numerous exceptions to any established criteria for waiting time accrual may yield complexity beyond what is reasonable for this relatively small percentage of kidney candidates.) Additionally, the Committee requested an evaluation of the amount of time candidates were staying inactive after listing.

Dr. Brewer also alerted the Committee on the preliminary discussions exploring the possibilities of regionally sharing kidneys for pediatric candidates. To address some of the issues outlined during its February 3<sup>rd</sup> call, a memo has been drafted to solicit the Histocompatibility Committee's input.

### 1c. Thoracic Organ Allocation Policy Review

David Campbell, MD, Committee Chair, updated the Committee on a February 2011 teleconference the Committee's Thoracic Working Group had with the Heart Subcommittee of the Thoracic Organ Transplantation Committee (the Thoracic Committee). This call continued the ongoing evaluation of pediatric heart allocation and the current pediatric heart status codes. To summarize some of the data that guided the discussion:

- Across pediatric age groups, the two most common diagnoses at listing and at transplant were congenital diseases and dilated cardiomyopathy.
- Criterion (e) was most commonly reported with restrictive cardiomyopathy, dilated cardiomyopathy, congenital diseases and other diagnoses among pediatric candidates aged 1-10 and 11-17 added to the waiting list in Status 1A; and among pediatric recipients aged 1-10 and 11-17 transplanted in Status 1A.
- Status 1A pediatric registrations with dilated cardiomyopathy had a higher probability of transplant within 90 days of listing as compared to those with congenital diseases.
- Status 1A pediatric registrations with dilated cardiomyopathy had a lower probability of death within 90 days of listing as compared to those with congenital diseases.
- One-year Kaplan-Meier patient survival for Status 1A pediatric recipients aged <1 year was higher for dilated cardiomyopathy as compared to congenital diseases.
- One-year Kaplan-Meier patient survival for Status 1A pediatric recipients aged 1+ year was the highest for dilated cardiomyopathy, followed by hypertrophic cardiomyopathy, other diagnoses, congenital diseases and restrictive cardiomyopathy.

The Pediatric Heart Transplant Study group has been asked to help the committees analyze mechanical circulatory support data that the OPTN does not collect, but would be critical to making appropriate, informed recommendations for modification.

*In Utero listings* The Thoracic Committee discussed the currency of the policies that allow *in utero* listings, and requested that the Committee comment on this. The general sentiment was that listing *in utero* candidates, and the corresponding transplant process, is rarely performed today. Committee members questioned listing an *in utero* candidate based on the minimal amount of information about the candidate that can be attained before birth. A Committee member recommended that the *in utero* policies be eliminated. The Committee agreed with this recommendation, but members wanted to speak with other colleagues specializing in heart transplantation to gauge how this may be received in the community before moving forward with a policy proposal. If significant objections are not identified, the next time the Committee convenes it will make a motion to develop a proposal for public comment to address this matter.

### 2. Addition of Pediatric Transplantation Experience Considerations in the Bylaws

Dr. Kim provided background regarding how the Committee originally became involved with this issue. Currently, there are no pediatric experience requirements in the bylaws that describe the necessary qualifications for key personnel at a transplant center. The bylaws' silence on this matter yields the potential that a primary surgeon or primary physician who has no pediatric transplant experience, but meets all the criteria in the bylaws, could be approved for a transplant center that predominately serves pediatric candidates. The Committee's past discussions revealed that it sees this as a deficiency of the bylaws that will require significant effort to modify. Before exerting this effort, the Committee had recommended that this matter be discussed by the Policy Oversight Committee (POC) to gauge the level of support for such a proposal. Dr. Kim reported that the POC indicated this is something that should be pursued, and now is an appropriate time to do so.

Committee members questioned if including such provisions was a duplication of efforts and responsibilities of those institutions that would be hiring these professionals; especially considering outcome reviews that are performed. Would a hospital hire an unqualified professional, and risk patient lives along with their reputation as a transplant center? Another Committee member responded that if the responsibility for appropriate decision making is to be left solely with the hospital, then this rationale should be applied universally to all transplant professionals; however, specific criteria already exist in the bylaws for “adult” programs. This indicates a previous determination of value in having mandatory experience criteria in addition to an institution’s responsible decision making. Accordingly, it seems reasonable to assure that those serving pediatric candidates, and their unique situations, also have appropriate backgrounds and experience. He continued that there are numerous issues that will need to be considered, and that some controversy is to be expected, but that this bylaw deficiency must be addressed. The intent is not to exclude successful programs from doing pediatric transplants; the intent is to provide some broad, logical rules to increase pediatric patient safety.

With patient safety in mind, the Committee opined that all transplant centers that perform pediatric transplants should be expected to meet these requirements, not just those that primarily serve pediatric candidates. If these requirements are only expected of centers that primarily serve pediatric candidates, then a significant number of pediatric candidates would not be afforded the same safety measures and quality of care that would be the intended consequence of adding pediatric experience requirements in the bylaws. The outcomes of centers that do the occasional pediatric transplant is more concerning than those centers that focus on pediatric care.

Another Committee member cautioned that this endeavor has the potential to uncover systems issues at individual centers. Having the appropriate support services available for a pediatric transplant is also critical to maximize patient care. Another Committee member pointed out that this issue is also unique as there is minimal data available to analyze the problem. Committee members responded that outcome data is readily available and could be reviewed. The Committee was reminded that similar information had been analyzed in the past, but the volume is too small to yield significant conclusions.

Dr. Campbell reminded the Committee that one of its charges is to develop policy that fosters good transplant outcomes for pediatric patients. It is his opinion that modifying the bylaws to include some pediatric experience requirements is absolutely necessary and very much aligned with this charge. This is and will continue to be a challenge to address, but progress will never be made if the Committee continues to remain inactive on this topic. The Committee unanimously (20 support, 0 oppose, 0 abstain) supported a motion to develop pediatric experience criteria to be added to the bylaws that all centers performing pediatric transplants would be expected to meet. Committee members stated that program and primary physician/surgeon requirements (organ specific) needed to be developed for those centers doing pediatric transplants. Defining these criteria will align with what is currently defined in the bylaws. The Committee indicated that a subcommittee, including representatives from the committee that are specialists in each organ group, could begin to work on program requirements.

### 3. Review and Consideration of Public Comment Proposals Released March 2011

3a. Proposal to Improve the Reporting of Living Donor Status The Living Donor Committee liaison presented this proposal for the Committee. After brief discussion, the Committee unanimously supported the proposal (20 support, 0 oppose, 0 abstain).

3b. Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels and Tissue Typing Materials The Living Donor Committee liaison continued to present this proposal for

the Committee. The Committee did not have any questions or concerns, and unanimously supported the proposal (20 support, 0 oppose, 0 abstain).

3c. Proposal to Standardize Label Requirements for Vessel Storage and Vessel Transport The Organ Procurement Organization (OPO) Committee Vice Chair, Richard Pietroski, MS, CPTC, presented the proposal for the Committee. The Committee did not have any questions or concerns, and unanimously supported the proposal (20 support, 0 oppose, 0 abstain).

3d. Proposal to Update and Clarify Language in the DCD Model Elements Mr. Pietroski continued with presenting this proposal for the Committee's consideration. After minimal discussion, the Committee unanimously supported the proposal (20 support, 0 oppose, 0 abstain).

3e. Proposal to Require Confirmatory Subtype Testing of Non-A1 and Non-A1B Donors The Operations and Safety Committee liaison presented this proposal for the Committee. The Committee did not have any questions or concerns, and unanimously supported the proposal (20 support, 0 oppose, 0 abstain).

3f. Proposal for Improved Imaging Criteria for HCC Exceptions Dr. Kim reviewed this proposal for the Committee. The Committee did not vote on this proposal as it did not believe that the modifications would have a direct or indirect impact on pediatric patients.

3g. Proposal to Reduce Waiting List Deaths for Adult Liver-Intestine Candidates Dr. Kim presented this proposal for the Committee. A Committee member questioned if data had been gathered to see how this might impact pediatric liver-intestine candidates. In response, the Committee recognized that pediatric candidates are rarely transplanted with livers/bowels from an adult donor. Accordingly, this impact on pediatric transplant candidates is probably small. Another Committee member, alluding to discussions had the Region 9 meeting, expressed concern that this policy change will make it even more difficult for isolated liver candidates to receive suitable offers. There were also concerns raised that there can be some variability in short bowel diagnoses, possibly leading to inconsistent listings. The Committee ultimately voted to support the proposal (19 support, 1 oppose, 0 abstentions).

3h. Proposed Committee-Sponsored Alternative Allocation System for Split Liver Allocation Dr. Kim presented this proposal for the Committee. The Committee expressed some of the same concerns it had with the Region 2 and OneLegacy split liver alternative allocation system (AAS) proposals that were distributed in the spring 2010 public comment cycle. Specifically, the Committee is concerned with the possibility of an increase in adult-adult split liver procedures, how stand-alone pediatric centers will be affected by this committee sponsored alternative system (CAS), and potential issues with a center attempting to increase their transplant volume at the expense of some transplant recipients who may not be ideal for split liver transplantation.

The Committee indicated it understood the Region 2 and OneLegacy split liver alternative allocation systems were to be trials, and questioned expanding these types of systems without any data to evaluate the results of those recently approved split liver AASs. A Committee member recalled past Liver Committee efforts to increase split liver transplantation had considered the strategy being proposed in the CAS. He indicated those efforts were curtailed because of feedback that this allocation strategy was in opposition with the Final Rule, in that organs needed to be allocated by need and not center preference. Accordingly, he was surprised there were no references to the Final Rule during the Board of Directors' discussion of these split liver AASs, and the subsequent recommendation to pursue the current CAS proposal.

The Committee unanimously opposed a motion (0 support, 20 oppose, 0 abstentions) to support the proposal. The following comments detail its opposition:

- The Committee is concerned with the possibility of an increase in adult-adult split liver procedures as a result of the proposed CAS. There is a lack of robust data showing comparable results for adult-adult split transplants versus whole liver grafts. An increase in these adult/adult split liver procedures could result in a greater number of poor outcomes for these adult recipients, which may decrease pediatric access. The predicted decreased pediatric access is on account of an increased possibility of failing adult-adult segmental transplants, which could yield two adult candidates with fulminant liver failure resulting in a situation where three livers are used to transplant two adults.
- The Committee is concerned with how stand-alone pediatric centers will be affected by this CAS. The Committee believes that exclusion of these stand alone pediatric programs from the proposal will create a disparity in access to transplant for pediatrics across the region. Candidates listed at pediatric programs affiliated with adult programs will have an advantage as compared to those listed at pediatric only programs.
- The Committee is concerned with possible consequences of allowing transplant centers to allocate the second lobe of the liver. The Committee thought these provisions could result in centers simply picking who should be transplanted, only to later enter broad refusal codes for any potential transplant recipient that the match run had prioritized higher than the second lobe recipient. The Committee also fears that this allocation strategy could foster a scenario where internal transplant center pressures and financial considerations of increased transplant volume could affect the decision making process as to whether a candidate on their waiting list should be transplanted with the second segment of the split liver graft.
- The Committee is concerned that bypassing potential transplant recipients on a match run because they are not listed at the same center as the index patient is in conflict with a goal of the Final Rule to distribute organs in order of decreasing medical urgency, as indicated in §121.8 (b)(2) and (3).

3g. Proposal to Encourage Organ Procurement Organizations (OPO) to Provide Computed Tomography Scan if Requested by Transplant Programs, And to Modify Language in 3.7.12.3 for Currency and Readability Steven Webber, MB, ChB, Pediatric/Thoracic Committee crossover representative presented the proposal for the Committee. The Committee did not have any questions or concerns, and unanimously supported the proposal (19 support, 0 oppose, 0 abstain).

3h. Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with Lung Allocation Scores (LAS) of at Least Fifty, And to Modify Policy 3.7.6.3 for Currency and Readability Dr. Webber presented this proposal for the Committee. The Committee did not have any questions or concerns, and unanimously supported the proposal (19 support, 0 oppose, 0 abstain).

3i. Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts Thirty Days of Status 1A Time Dr. Webber also presented this proposal for the Committee. After minimal discussion, the Committee supported the proposal (17 support, 0 oppose, 2 abstain).

OPTN/UNOS Pediatric Transplantation Meeting  
 April 11, 2011  
 Chicago, Illinois

<b>NAME</b>	<b>COMMITTEE POSITION</b>	<b>In Person</b>
David Campbell, MD	Chair	X
Heung Bae Kim, MD	Vice Chair	X
Simon Horslen, MB, ChB	Ex-Officio	X
Scott Elisofon, MD	Regional Representative	X
George Mazariegos, MD, FACS	Regional Representative	X
Alfonso Campos, MD	Regional Representative	X
Carmen Cosio, MD	Regional Representative	
Debra Strichartz, RN, BA, CCTC	Regional Representative	X
Andre Dick, MD	Regional Representative	X
Nissa Erickson, MD	Regional Representative	X
Jeffrey Lowell, MD	Regional Representative	
Kishore Iyer, MD	Regional Representative	X
Jeff Shuhaiber, MD	Regional Representative	X
Kathy Jabs, MD	Regional Representative	X
Todd Astor, MD	At Large	
Sandra Amaral, MD	At Large	X
Eileen Brewer, MD	At Large	X
Michael Chobanian, MD	At Large	
Sam Davis	At Large	X
Shylah Haldeman, RN	At Large	X
Manuel Rodriguez-Davalos, MD	At Large	X
Kenny Laferriere, BSW	At Large	X
Thomas Nakagawa, MD	At Large	X
Anthony Savo, MD	At Large	
Steven Webber, MB, Chb	At Large	X
Jerry Wright, RN, CPTC	At Large	
Monica Lin, PhD	HRSA	via phone
Ba Lin, MS, MPH	HRSA	via phone
Jodi Smith, MD	SRTR	X
Jon Snyder, PhD, MS	SRTR	X
Mary Carpenter	Visiting Board Member	X
Jory Parker	UNOS Business Analyst	via phone
Wida Cherikh, PhD	UNOS Research	X
Chad Waller, MS	Committee Liaison	X
Lee Bolton	Committee Liaison	via phone
Kimberly Taylor, RN	Committee Liaison	via phone