

OPTN/UNOS Pediatric Transplantation Committee
Report to the Board of Directors
June 28-29, 2011
Richmond, Virginia

Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items

- The Committee discussed OPTN Final Rule requirements for organ allocation policy development. (Item 1, Page 3)
 - Liver Allocation Policy Review. (Item 1a, Page 3)
 - Kidney Allocation Policy Review. (Item 1b, Page 9)
 - Thoracic Organ Allocation Policy Review. (Item 1c, Page 10)
- The Committee discussed adding of pediatric transplantation experience considerations in the bylaws. (Item 2, Page 11)
- The Committee considered policy and bylaws proposals distributed for public comment. (Item 3, Page 12)
 - Proposals issued on October 1, 2010. (Item 3a, Page 12)
 - Proposal issued on January 21, 2011. (Item 3b, Page 14)
 - Proposals issued on March 11, 2011. (Item 3c, Page 14)

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

The following report presents the OPTN/UNOS Pediatric Transplantation Committee's deliberations and recommendations on matters considered during its December 8, 2010, and April 11, 2011, meetings.

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

1a. Liver Allocation Policy Review.

Split Liver Allocation Modification- At its April 2011 meeting, 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 2nd 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 23rd discussion centered on a modified iteration of the concept based on previous comments. At the end of the Liver Committee's March 23rd discussion, it approved a motion (8-support, 6-oppose, 3-abstain) to support the modified concept as it was proposed.

UNOS staff reviewed data analyses resulting from 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. These data were 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, the age distribution of right lobe recipients when the index patient was a child (i.e., the first candidate on the match who accepted the liver was a pediatric). 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+.

These data showed that adult potential transplant recipients are accepting and being transplanted with split liver grafts. These data indicated that left lateral segment splits rarely result in wastage

of the second liver segment, allowing 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 donors where it was later realized that the anatomy of the liver precluded it from being safely split for two transplants.

The necessity for increased pediatric priority and access is commonly questioned when discussing modifications to split liver allocation. To investigate this, the February 2011 joint-Pediatric/Liver Committee 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 from the liver waiting list for being too sick. 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.)

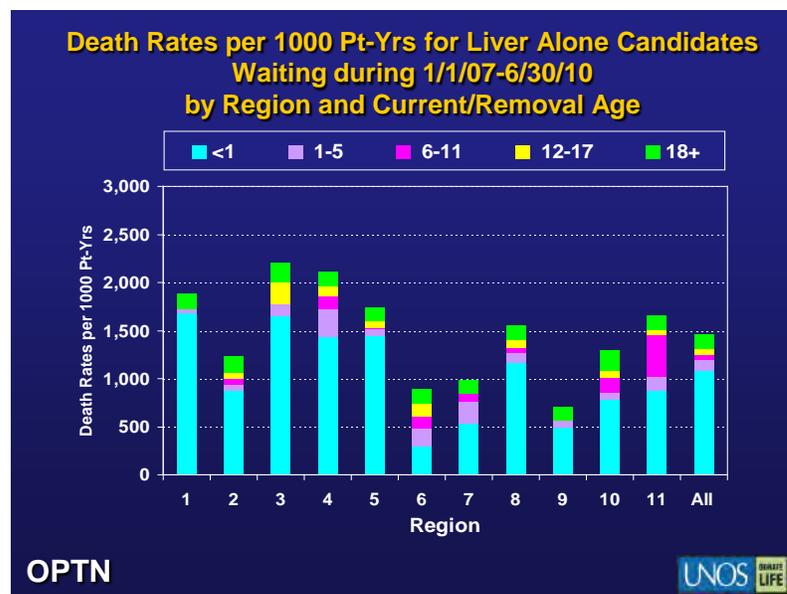


Figure 1: Death rates per 1000 patient-years for liver alone candidates waiting during 1/1/07-6/30/10 by region and current/removal age

The second part of the data request analyzed those candidates who were removed from the waiting list for death or being too sick for transplant. The following, and Table 1, summarize 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.
- There were 18 patients with >0 active days on the waiting list who 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
Total	19	11	7	12	2	51

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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 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, the number of offers ranged from 1 to 29.
- There were 11 patients with >0 active days on the waiting list who 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
Total	16	7	4	3	0	30

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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)

While reviewing the diagnosis category data, the Committee requested a comparison of these percentages relative to the distribution of diagnoses for those pediatric candidates currently on the liver waiting list. In addition, the Committee requested further detail concerning the 41% of pediatric candidates who died on the liver waiting list and cited “other.”

The Committee commented that the trend of MELD/PELD scores at the time of removal tending to be higher than those scores at the time of listing proves that a child who has a low MELD/PELD score faces a significant risk of death on the waiting list. These data are important in addressing concerns 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, indicate 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 who 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 pediatric 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 for 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.¹

Using these and OPTN data, 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% of those livers from 18-34 year olds, and 1.1% of all deceased donor livers. This difference can be attributed to the current pediatric donor allocation system that allocates livers from deceased donors less than 18 years old to pediatric recipients after local/regional Status 1A and 1B candidates. When one of these 16-17 year old donor livers is allocated to a small child, the liver must be split for size reasons, and the remaining liver segment is reallocated, usually to an appropriate adult recipient. In order to estimate the number of split livers that would result from increasing the age of this pediatric preference, the 6.7% split rate seen in 16-17 year old donors was applied to the total number of donors that could be expected (based on donor data from 2008) if the proposed pediatric priority was implemented for deceased donors less 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.

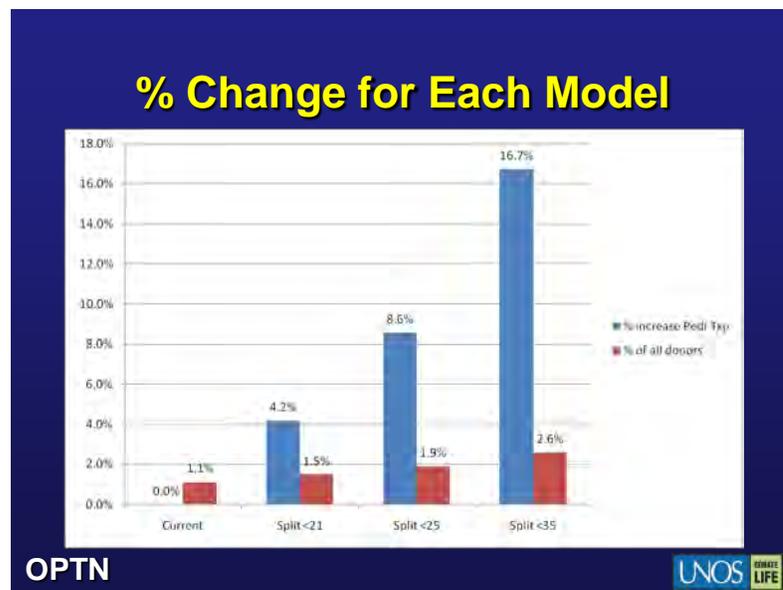


Figure 2: Theoretical percentage increase of the number of livers split when the 6.4% split rate is applied to the number of donors under the age of 21, 25, and 35, respectively.

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

¹ 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.

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 that 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 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. 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. Without that feedback, the Committee was hesitant to 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).

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-

During the Committee's April 2011 meeting, 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 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.
- There were very few liver-intestine alone transplants done in adolescents or adults.

Evaluation of New Pediatric Specific Data Elements Added to the Liver and Intestine Forms on 3/1/2008- During the April 2011 meeting, 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.

1b. Kidney Allocation Policy Review.

At the April 2011 meeting, Eileen Brewer, MD, Kidney Transplantation Committee (Kidney Committee) crossover representative, updated the Committee on the current developments of 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 18th birthday as a pediatric, even after their 18th birthday. The Committee's Working Group discussed this at its February 3rd conference call, and requested some data to evaluate these concerns. The Kidney Working Group agreed that a patient on dialysis obviously should be accruing waiting time, and focused on the estimated creatinine clearances for those kidney candidates who are preemptively transplanted. The standard Schwartz formula for pediatrics was used to estimate glomerular 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 further 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- To summarize the results from the requests made by the Kidney Working Group during its February 3rd conference call:

- About one-third of pediatric candidates added to the kidney alone waiting list were not on dialysis at listing.
- 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.
- Inactive listings are common at every age 0-17. 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 Committee stated the questions that need to be addressed are whether pediatric candidates would be disadvantaged by a minimal GFR to initiate waiting time; and, if a minimal GFR is appropriate, would that indirectly result in transplant centers listing more candidates at an inactive status? The Committee 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. Working Group members opined 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. The Committee suggested that 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. Accordingly, it requested the diagnoses of these 53 transplant recipients be more thoroughly investigated. Two possible diagnoses were mentioned that would need a transplant at a higher GFR, mid-aortic syndrome and congenital nephrotic syndrome. These conditions would need to be considered as exceptions to any established GFR for initiating the accrual of waiting time. Additionally, the Committee requested an evaluation of the amount of time candidates were staying inactive after listing.

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

1c. Thoracic Organ Allocation Policy Review.

During the Committee's April 2011 meeting, 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 to modify policy.

In Utero listings The Thoracic Committee recently 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 candidate information that can be attained before birth. A Committee member recommended that the *in utero* policies be eliminated. The Committee supported this recommendation, but before moving forward with a policy proposal, members wanted to speak with other colleagues specializing in heart transplantation to gauge how this may be received in the community. If significant objections are not identified, the next time the Committee convenes it will motion to develop a proposal for public comment to address this matter.

2. Addition of Pediatric Transplantation Experience Considerations in the Bylaws

During the Committee's December 2010 meeting held via teleconference, UNOS staff provided some history regarding past committee discussions about this topic, and alluded to recent applications reviewed by the Membership and Professional Standards Committee (MPSC) that has brought this matter back to the forefront. The bylaws' silence on pediatric transplant experience requirements 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 feels this is a critical issue that has been habitually passed from committee to committee, with very little progress because this is a large, intricate, and somewhat controversial topic. Members commented that if the Committee is interested in thoroughly addressing all the details of this issue, with subsequent recommendations for the MPSC and Board of Directors, the Committee must be fully committed to this effort with the support of OPTN/UNOS leadership. Otherwise, it is anticipated that another attempt to address this issue will likely end with little resolution, as has occurred in the past. Echoing these sentiments, the Committee Chair mentioned that unless there is a strong commitment and willingness to support the Committee's recommendations, he questioned the value of spending Committee time addressing experience criteria for primary surgeons and physicians at transplant programs serving pediatric patients. Considering this, call participants agreed that the Committee should gauge the organization's leadership's level of support for these endeavors before efforts are initiated again. As the Policy Oversight Committee (POC) is comprised of committee vice chairs, the Committee decided to send it a memo requesting feedback to help determine the level of support for this effort.

At its April 2011 meeting, Dr. Kim reported on the POC's discussion resulting from the Committee's request. Dr. Kim stated that the POC indicated this is something that should be pursued, and now is an appropriate time to do so.

Committee members questioned if establishing pediatric experience requirements is 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. The intent is not to exclude successful programs from doing pediatric transplants; rather, it 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 to the bylaws. The outcomes of centers that do the occasional pediatric transplant are more concerning than those centers that focus on pediatric care.

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 of Policies and Bylaws Issued for Public Comment

3a. Proposals issued on October 1, 2010.

Proposal to Clarify which Transplant Program has Responsibility for Elements of the Living Donation Process and to Reassign Reporting Responsibility for Living Donation from the Recipient Transplant Program to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy- The Committee indicated general support for the proposal.

Considering these proposed changes, and those centers that will only be involved with transplanting the living donor’s organ, a committee member questioned if these policy and bylaw changes will require these recipient hospitals to have internal policies and protocols addressing the donation side of the living donor transplant process (i.e. donor work-ups, donor selection criteria, etc.). It was requested that it be clarified whether or not the recipient hospital would be expected to have these living donor protocols documented. If so, would only referring to the donor hospital’s protocols suffice? There was concern of possible confusion and compliance issues if the living donor recovery and the living donor recipient centers’ policies and protocols are in conflict.

The Committee unanimously supported (14- support, 0-oppose, 0-abstain) a motion to approve this proposal as written.

Proposal to Require Collection of Human Leukocyte Antigen (HLA) Type for Thoracic Organs- The Committee had minimal discussion on this topic. It unanimously supported (14- support, 0-oppose, 0-abstain) a motion to approve the proposal as written.

Proposal to Clarify Adult Heart Status IA Language to Enable Consistent Interpretation of Policy and Reflect Current Programming in UNetSM- Members had individually reviewed the proposal and the Committee agreed that there was no specific pediatric issue requiring comment. Accordingly, the Committee did not formally discuss or vote on this proposal.

Proposal to Prohibit Storage of Hepatitis C Antibody Positive and Hepatitis B Surface Antigen Positive Extra Vessels- Committee members indicated that this is unlikely to have a significant impact on pediatric patients, but expressed unease with such a broad policy relative to the infrequent occurrence of these events. The Committee questioned changing policy because of mistakes made by a few centers, when a significant number of other centers throughout the transplant community have procedures and practices in place that have effectively mitigated the risks associated with storing these serologically positive vessels. To this point, committee members suggested that a deliberate process (multiple signatures for verification, time out, documentation why the particular vessels to be used are necessary, etc.) be used to avoid the risks associated with storing these serologically positive vessels instead of completely prohibiting their storage. Ultimately, the Committee felt that these policy changes may potentially do more harm than good.

After discussion, the Committee unanimously approved (16- support, 0-oppose, 0-abstain) a motion to oppose the proposal.

Proposal to Establish Qualifications for Director of Liver Transplant Anesthesia in the Bylaws- A Committee member asked if there was a particular reason why the bylaws only address requirements for a director of liver transplant anesthesia, and not the whole team. Staff replied that the changes being pursued are similar to what is currently in the bylaws for the designation of a primary surgeon or a primary physician. That is, the development of requirements for a role to provide leadership to the rest of the team and to promote consistent involvement in the program by the person that fills this roll. To this point, there are no immediate plans to establish qualifications for the rest of the anesthesia team.

As the MPSC had not yet formally addressed whether the current case volume requirement in the proposal (20 over five years) is appropriate for directors of anesthesia at primarily pediatric centers, UNOS staff asked the Committee for its opinion. Committee members from different regions commented that the requirements in the proposal should be adequate for any liver transplant program, primarily pediatric or otherwise.

A Committee member questioned if a timeframe for centers to meet this requirement had been established. UNOS staff indicated that the MPSC had not yet discussed this as it anticipated that most centers have someone that is qualified. Nevertheless, this will need to be determined and will be brought to the MPSC's attention during its next discussion regarding this proposal.

The Committee unanimously supported (16- support, 0-oppose, 0-abstain) a motion to approve the proposal as written and request that the MPSC detail a time frame to meet the requirements in the proposal if a center does not already have a qualified candidate to fill the director of liver

transplant anesthesia role. Additionally, the Committee agreed to communicate that the current case volume in the proposal also seems reasonable for primarily pediatric centers.

Proposal to Modify the Requirements for Transplant Hospitals that Perform Living Donor Kidney Recoveries- After minimal discussion, the Committee unanimously supported (16- support, 0- oppose, 0-abstain) a motion to approve the proposal as written.

3b. Proposal issued on January 21, 2011.

Proposed Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization- The Committee individually reviewed the proposal and agreed that there was no specific pediatric issue requiring comment. Accordingly, the Committee did not formally discuss or vote on this proposal.

3c. Proposals issued on March 11, 2011.

Proposal to Improve the Reporting of Living Donor Status- After brief discussion, the Committee unanimously supported the proposal (20 support, 0 oppose, 0 abstain).

Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels and Tissue Typing Materials- The Committee did not have any questions or concerns, and unanimously supported the proposal (20 support, 0 oppose, 0 abstain).

Proposal to Standardize Label Requirements for Vessel Storage and Vessel Transport- The Committee did not have any questions or concerns, and unanimously supported the proposal (20 support, 0 oppose, 0 abstain).

Proposal to Update and Clarify Language in the DCD Model Elements- After minimal discussion, the Committee unanimously supported the proposal (20 support, 0 oppose, 0 abstain).

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

Proposal for Improved Imaging Criteria for HCC Exceptions-The Committee did not formally discuss or vote on this proposal as it did not believe that the modifications would have a direct or indirect impact on pediatric patients.

Proposal to Reduce Waiting List Deaths for Adult Liver-Intestine Candidates- 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, modifying these policies will likely have a minimal impact on pediatric transplant candidates. 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 variability in short bowel diagnoses, which may lead to inconsistent listings. The Committee ultimately voted to support the proposal (19 support, 1 oppose, 0 abstentions).

Proposed Committee-Sponsored Alternative Allocation System for Split Liver Allocation- 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 this type of system 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 (0 support, 20 oppose, 0 abstentions) 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 donation service area or region. Candidates listed at pediatric programs affiliated with adult programs will have an advantage as compared to those listed at stand-alone pediatric centers.
- 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).

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- The Committee did not have any questions or concerns, and unanimously supported the proposal (19 support, 0 oppose, 0 abstain).

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- The Committee did not have any questions or concerns, and unanimously supported the proposal (19 support, 0 oppose, 0 abstain).

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

OPTN/UNOS Pediatric Transplantation Meeting
December 8, 2010
Live Meeting/teleconference

NAME	COMMITTEE POSITION	On the Call
David Campbell, MD	Chair	X
Heung Bae Kim, MD	Vice Chair	X
Simon Horslen, MB, ChB	Ex-Officio	
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	X
Kishore Iyer, MD	Regional Representative	
Jeff Shuhaiber, MD	Regional Representative	
Kathy Jabs, MD	Regional Representative	
Todd Astor, MD	At Large	X
Sandra Amaral, MD	At Large	X
Eileen Brewer, MD	At Large	X
Michael Chobanian, MD	At Large	X
Sam Davis	At Large	X
Shylah Haldeman, RN	At Large	
Manuel Rodriguez-Davalos, MD	At Large	X
Kenny Laferriere, BSW	At Large	
Thomas Nakagawa, MD	At Large	
Anthony Savo, MD	At Large	
Steven Webber, MB, Chb	At Large	X
Jerry Wright, RN, CPTC	At Large	
Monica Lin, PhD	HRSA	
Ba Lin, MS, MPH	HRSA	X
Jodi Smith, MD	SRTR	X
Sally Gustafson	SRTR	X
Mary Carpenter	Visiting Board Member	X
Jory Parker	UNOS Business Analyst	X
Wida Cherikh, PhD	UNOS Research	X
Chad Waller, MS	Committee Liaison	X
Lee Bolton	Committee Liaison	X
Vipra Ghimire, MPH, CHES	Committee Liaison	X
Kimberly Taylor, RN	Committee Liaison	X
Sally Aungier	Committee Liaison	X
Dave Kappus, MAS	Director, UNOS Membership	X
Brian Shepard	Director, UNOS Policy	X

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

NAME	COMMITTEE POSITION	In Person
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