

OPTN/UNOS Pediatric Transplantation Committee Summary

Action Items for Board Consideration

- None

Other Significant Items

- The Committee discussed OPTN Final Rule requirements for organ allocation policy development. (Item 1, Page 3)
 - Thoracic organ allocation. (Item 1a, Page 3)
 - Liver and intestinal organ allocation. (Item 1b, Page 9)
 - Kidney allocation. (Item 1c, Page 12)
 - Pancreas allocation. (Item 1d, Page 17)
- The Committee discussed concerns regarding recently implemented living donor follow-up requirements. (Item 2, Page 17)
- The Committee prepared to convene a Joint Subcommittee with the OPO Committee to discuss the development of best practices for administering pre-recovery medications and donor management. (Item 3, Page 18)
- The Committee considered policy and bylaws proposals distributed for public comment. (Item 4, Page 18)
- The Committee raised concerns regarding CMS volume requirements for approval to transplant young adults in pediatric transplant centers. (Item 5, Page 21)

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**REPORT OF THE OPTN/UNOS PEDIATRIC TRANSPLANTATION COMMITTEE
TO THE BOARD OF DIRECTORS**

**Orlando, Florida
February 20-21, 2008**

**Stuart C. Sweet, MD, PhD, Chair
Simon Horslen, MB ChB, Vice Chair**

The following report presents the OPTN/UNOS Pediatric Transplantation Committee's deliberations and recommendations on matters considered during its July 12, 2007, and November 29, 2007, meetings.

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

1a. Thoracic Organ Allocation Policy Review

Heart-Lung Working Group Update In July 2007, Dr. Stuart Sweet, the Heart-Lung Working Group Chair provided members with a brief update regarding the latest round of data that were reviewed (**Exhibit A**), and preliminary recommendations for policy modifications that are expected to be released for public comment in February 2008. The Committee voted unanimously (17-0-0) to share the Working Group recommendations with the Thoracic Committee during its October 2, 2007, meeting to begin building consensus for broader sharing of pediatric hearts and lungs prior to public comment. The Committee hoped to release the heart and lung proposals jointly sponsored with the Thoracic Committee.

During the November 2007, meeting, Dr. Sweet provided the full Committee with an overview of progress made and data reviewed during its September 25, 2007, conference call (**Exhibit B**). Separate heart and lung proposals were under development based on the Working Group's progress over the last 18 months. He also shared feedback from his presentation to the Thoracic Committee on October 2, 2007. Thoracic members were supportive of the Working Group's direction and amenable to the idea of a joint proposal.

Members reviewed a table comparing current heart allocation policy versus the suggested modifications developed by Working Group members (**Exhibit C**). The heart proposal will specifically address the allocation of young pediatric donor hearts (defined here as age 0-10 yrs). Although adolescent (11-17 year old) donor hearts are allocated preferentially to pediatric candidates before adult candidates within status codes and geographic zones, young pediatric donor hearts are not. Though not specifically referenced in current policy, these small hearts are currently allocated using the same algorithm in place for adult donors. The intent of the new policy language will be to share young pediatric donor hearts more broadly, combining local and Zone A offers for Status 1A pediatric candidates and for 1B pediatric candidates respectively. In addition, the remaining pediatric candidates will receive offers for young pediatric donor hearts before adults within each status and allocation zone in an effort to direct these small organs first to younger children. Because historically, only 0.5% of adults and 12% of adolescents have received hearts from donors younger than 12 years old, the Working Group believes that prioritizing pediatric candidates for these organs ahead of adults should have a limited impact on adults while reducing pediatric waiting list mortality.

Upon review, a member suggested that all pediatric donors (0-17 years of age) follow the suggested algorithm, putting local and zone A into the same category for adolescent donors as well. This would simplify programming and not have any additional effect on adults. Broader

sharing within status may make getting support from centers with a large number of adolescent candidates more difficult, but members were supportive of offering both scenarios to the Thoracic Committee. Though the potential for more travel to retrieve organs is a potential concern to transplant programs, wait time should theoretically be reduced for candidates.

The Committee voted unanimously (18 yes, 0 no, 0 abstentions) to authorize the Heart-Lung Working Group to finalize this proposal on its behalf for the upcoming February public comment cycle.

The Working Group's draft lung proposal specifically addressed allocation to young pediatric lung candidates (defined here as age 0-11 yrs). Members reviewed a table comparing current lung allocation policy versus suggested modifications developed by Working Group members (**Exhibit D**). In May 2005, the method for allocating lungs in the United States was updated. For adolescent (aged 12 and up) and adult candidates on the waiting list, allocation by waiting time was replaced by the lung allocation system (LAS). The LAS score, calculated using each individual's medical information, prioritizes candidates based on a combination of waiting list mortality and predicted survival benefit. For young pediatric candidates, however, within each allocation zone and blood type, lungs remain allocated based on waiting time. There are two components to the proposed policy changes:

- (1) The first would create a simple stratified system for young pediatric candidates (based on objective medical characteristics) to direct donor lungs to the sickest of these candidates first. Dr. Sweet informally polled pediatric lung programs regarding all current and recent candidates to determine where they fell into the two categories below:

Status 1 Criteria for lung candidates 0-11 yrs old:

1) Respiratory failure:

- a) Full time Mechanical Ventilation *or*
- b) supplemental oxygen requirement > 6 liters per minute by nasal cannula or 50% face mask required to maintain oxygen saturation > 90% *or*
- c) PCO₂ > 50.

or

2) Refractory pulmonary vascular disease:

- a) Treatment failure (Any of: suprasystemic PA pressure on catheterization or by echocardiogram estimate, Cardiac Index < 2, recurrent syncope or hemoptysis) while on 2 or more drug therapy *or*
- b) patients with pulmonary vein stenosis involving 3 or more vessels

or

3) exceptional cases by prospective submission to a review board

Status 2: all remaining candidates

The youngest patients were usually the sickest, as expected. Such a system was agreed upon as expected to move the sickest 0-11 year-olds to the top of the match run in much the same way that LAS functions for adolescents and adults.

- (2) The second proposes broader sharing for young pediatric donor lungs, allocating first to local, Zone A and Zone B young pediatric candidates, and then to local and Zone A adolescents before local offers are made to adults. Because size matching limits suitability of pediatric donors to adults, historically, only 0.4% of lungs from pediatric donors have been transplanted into adults. These proposed changes should have a limited impact on adults while reducing pediatric waiting list mortality.

A member questioned whether heart-lung match runs would also be impacted by these suggested modifications. Due to the very small numbers, Dr. Sweet was uncomfortable with recommending any changes in the draft proposal to be shared with the Thoracic Committee, but agreed that this was an area of discussion that could be considered when the Working Group members meet with Thoracic Committee representatives to discuss the proposal.

The Working Group will meet with the Thoracic Committee's Heart and Lung Subcommittees as a Joint Subcommittee to review these proposals and suggest the idea of releasing these proposals as a joint effort between the committees to reflect consensus on changing the current allocation algorithm to better serve these young children. This meeting is anticipated in January 2008.

The Committee voted unanimously (19 yes, 0 no, 0 abstentions) to authorize the Heart-Lung Working Group to finalize this proposal on its behalf for the upcoming February public comment cycle.

Joint Pediatric-MPSC Data Subcommittee The Committee heard a summary report from the May 11, 2007 Joint Pediatric- Membership and Professional Standards Subcommittee (MPSC) teleconference during its July meeting (**Exhibit E**). This group considered concerns related to the outcomes review process for pediatric lung programs. The SRTR was studying whether the ≤ 11 year-old and ≥ 12 year-old subsets could be combined for outcomes review. This distinction was created due to differences in pre-transplant mortality related to the current LAS system for allocation. The post-transplant model is not as divergent, and preliminary results indicate that a combined model may serve the pediatric population as a whole for the MPSC's monitoring requirements. The final results of the SRTR's modeling will be shared in a follow-up call with the Joint Subcommittee.

The Committee received a brief update on this project during its November 2007, meeting. Center Specific Reports (CSRs) and outcome tracking measure adolescents and adults with the LAS system, creating an artificial division in pediatric lung programs. These programs can be flagged by the MPSC for either population as a result. Separating all pediatric candidates from adults raised new concerns regarding outcomes that need further discussion in this upcoming call. In reality, this change did not benefit pediatric programs, but several more adult programs were flagged for their new pediatric programs than before- a potential cause for concern. Dr. Sweet suggested that comparison of survival of adolescents cared for in predominantly adult programs versus predominantly pediatric programs would be an appropriate analysis to consider. This group will reconvene in late January to review the additional data.

Assess Impact of Broader Sharing of 0-11 Donor Organs for Pediatric 0-11 Lung and 0-18 Heart Candidates and Assess the Availability of Data for Potential Stratified Allocation of Lungs for 0-11 Pediatric Candidates The SRTR presented data assessing the impact of broader sharing of 0-11 donor hearts and lungs for pediatric candidates (**Exhibit F**) in July 2007 to aid the Working Group in developing its public comment proposals. This modeling also assessed the availability

of data for potential stratified allocation of lungs for pediatric candidates. The TSAM results did not show remarkably different outcomes for hearts or lungs in terms of the numbers transplants or wait list deaths. There did appear to be a slight increase in the number of adult post-transplant deaths, appearing consistently across all simulations.

It was noted that though the modifications were designed to increase the probability of a pediatric thoracic organs being allocated to a pediatric recipient, only 23 pediatric hearts and 12 pediatric lungs were allocated to adult recipients during the study period. More substantial changes appeared in broader geographic sharing of lungs for children, seen when Zone A sharing was extended to the current limits for Zone B.

LAS Update The Committee did not review the standard LAS update in July, but will continue to receive updates when there are significant changes with age distribution of pediatric organs and wait list mortality for 12-17 year olds. In November, The Committee was asked to review a report outlining the performance of LAS in its first two years independently after the meeting (**Exhibit G**). They were not presented during the meeting due to time constraints. One year outcomes are now available, and meeting the predictions made early on for the LAS system. This information will be revisited at a future meeting.

Estimate of Time Needed to Accrue Enough Data to Evaluate July 2006 Heart Policy Change for Pediatric Patients The Committee reviewed data in November to estimate how many years it would take to have a high enough number of wait list deaths in specifically defined age groups to observe statistical difference in death rates before and after heart policy changes implemented on July 12, 2006 (**Exhibit H**). Because of the small numbers involved in pediatric transplant, the shortest wait of such data was noted as the <1 year old group, at 63 months, and ranged upwards to 158 months for 6-10 year olds. Therefore, it was noted as impractical to wait for statistical significance to determine a path forward for policy change in heart allocation.

Clarification to Board-Approved Modifications to Policies 3.7.8 and 3.7.8.1, Extending ABO-Incompatible Heart Transplant to Children >1 Year Old UNOS staff presented suggested housekeeping changes to policies 3.7.8 (ABO Typing for Heart Allocation) and 3.7.8.1 (Heart Allocation to Pediatric Candidates Eligible to Accept a Donor Heart of Any Blood Type) during the November 2007 meeting (**Exhibit I**). These policy changes, approved by the Board of Directors in September 2006, were potentially confusing to the reader and difficult for programming staff to follow. Without changing the intent of the policy, language was re-drafted to offer clarity and step by step direction to the reader. Staff consulted with current and past Committee members involved in the original efforts to modify the language.

The Committee voted unanimously (19 yes, 0 no, 0 abstentions) to support taking these housekeeping modifications to the Executive Committee for approval in December in order to continue programming with the hopes of a spring 2008 implementation.

**The Executive Committee approved the changes as submitted during its December 18, 2007 conference call. This item appeared on the consent agenda and no discussion took place. The resolution and final policy modifications appear below.*

RESOLVED, that the following modifications to Policy 3.7.8 (ABO Typing for Heart Allocation) are hereby approved, effective December 18, 2007.

3.7.8 ABO Typing for Heart Allocation. Within each heart status category, hearts will be allocated to patients according to the following ABO matching requirements:

- (i) Blood type O donor hearts shall only be allocated to blood type O or blood type B patients;
- (ii) Blood type A donor hearts shall only be allocated to blood type A or blood type AB patients;
- (iii) Blood type B donor hearts shall only be allocated to blood type B or blood type AB patients;
- (iv) Blood type AB donor hearts shall only be allocated to blood type AB patients.
- (v) If there is no patient available who meets these matching requirements, donor hearts shall be allocated first to patients who have a blood type that is compatible with the donor's blood type.
- (vi) Following allocation for all born transplant candidates who have blood types that are compatible with donors, hearts will be allocated locally first and then within zones in the sequence described in 3.7.10, by heart status category to born Status 1A or 1B pediatric heart candidates who are eligible to receive a heart from any blood type donor. Allocation to *in utero* candidates eligible for any blood type donors is initiated after all eligible born candidates have received offers.

A center may specify on the waiting list that a candidate is eligible to accept a heart from any blood type donor if one of the following conditions is met:

- (i) Candidate is *in utero*;
- (ii) Candidate is less than 1 year of age, and meets all of the following:
 - a. Listed at Status 1A or 1B, and
 - b. Current isohemagglutinin titer information for A and/or B blood type antigens reported in UNetSM.
- (iii) Candidate is greater than or equal to 1 year of age, and meets all of the following:
 - a. Listed prior to age 2;
 - b. Listed at Status 1A or 1B;
 - c. Current isohemagglutinin titer level(s) less than or equal to 1:4 for A and/or B blood type antigens reported in UNetSM; and
 - d. Has not received treatments (such as plasmapheresis or transfusions) within the prior 30 days that could potentially alter spontaneously produced titer values.

~~Following allocation for all born transplant candidates who have blood types that are compatible with donors, hearts will be allocated locally first and then within zones in the sequence described in Policy 3.7.10, by heart status category to Status 1 pediatric heart candidates less than one year up to less than two years of age at time of listing identified as being compatible with **any** eligible to receive a~~

heart from any blood type donor. (typically based on having Eligibility is defined as age < 6 months 1 year old or recipient candidate isohemagglutinin titers less than or equal to 1:4 for A and/or B blood type antigens) for infants >6 months old > 1 year old who have a blood type that is incompatible with the donor's blood type if the candidate is been listed with the blood type "Z" designation as willing to accept a heart from a donor of any blood type. The isohemagglutinin titer used for recipient selection shall best reflect the recipient's candidate's responsiveness to spontaneous production of blood group antigens independent of modifiers, such as plasmapheresis or transfusions, within 30 days. When isohemagglutinin titers in recipientscandidates >6 months old >1 year old cannot be accurately determined due to modifiers received within 30 days that could potentially manipulate titer values, then status Z listing the candidate shall not be designated as eligible to accept donor hearts of any blood type under this policy used. Following allocation for born pediatric candidates who are eligible to accept donor hearts of any blood type "Z" incompatible pediatric heart candidates, less than one year of age, hearts will be allocated, locally first and then within zones in the sequence described in Policy 3.7.10, to patients listed *in utero*.

3.7.8.1 Heart Allocation to Pediatric Candidates Less Than 2 Years of Age Willing Eligible to Accept a Donor Heart of Any Blood Type. A center may specify on the waiting list that a candidate is eligible to accept a heart from any blood type donor if the eligibility requirements set forth in Policy 3.7.8 are met.

Anti-A and/or Anti-B titers must be reported:

- (i) At time of listing (except for *in utero* candidates);
- (ii) Every 30 days after listing (all eligible born candidates);
- (iii) At transplant; and
- (iv) In the event of graft loss or death within one year after transplant (for all candidates transplanted with other than blood type identical or compatible donor hearts.

Listing and transplant outcomes for candidates determined to be eligible under this policy will be monitored on a quarterly basis by a subcommittee of the Pediatric Transplantation Committee, including at least two non-Committee members with analytical and/or other professional expertise in this area of medicine, and reported to the Pediatric Committee. Transplant programs that list candidates for receipt of donor hearts of any blood type shall be required to provide information requested for review by the subcommittee, including, for example, autopsy reports.

For pediatric candidates less than two years of age at time of listing who meet the eligibility requirements set forth in Policy 3.7.8, including *in utero* candidates for whom blood type is unknown, centers may specify on the Waiting List those candidates who will accept a heart from a donor of any blood type., the blood type "Z" designation may be added

~~as a suffix to the actual blood type (e.g., "AZ") of a pediatric patient less than one year up to less than two years of age, or used alone if actual blood type is not known for *in utero* candidates. Patients older than two years of age may be listed with the type "Z" designation suffix upon an application by his/her transplant physician(s) providing justification to the applicable Regional Review Board. Timing of the review of these cases shall be prospective. Anti-A and anti-B titers shall must be reported at the times of listing, (except for *in utero* candidates), monthly after listing (all eligible candidates), at transplant and in the event of graft loss or death within one year after transplant (for candidates transplanted with other than blood type identical or compatible donor hearts). Listing and transplant outcomes for status Z candidates determined to be eligible under this policy will be monitored on a quarterly basis by a subcommittee of the Pediatric Transplantation Committee, including at least two non-Committee members with analytical and/or other professional expertise in this area of medicine, and reported to the Pediatric Committee. Transplant programs that list candidates with the blood type Z designation for receipt of donor hearts of any blood type shall be required to provide information requested for review by the subcommittee, including, for example, autopsy reports.~~

[No further Changes to Policy 3.7.8]

Expanding the Adolescent Candidate Window within the LAS Concerns were raised during the Thoracic Committee's October 2, 2007, meeting that members believed the LAS was being used to direct organs to older patients that could potentially benefit young adults. This was based on an anecdotal experience from a particular center where adolescent lungs were allocated to a 70 year old. A suggestion was made to expand the adolescent window in LAS, currently 12-17 years of age, upward to age 21 or 25. This would direct adolescent donor lungs to recipients up to either of these selected ages. The Thoracic Committee asked for this to be modeled, including its impact on pediatrics and overall outcomes. The Pediatric Committee was supportive of this suggestion during its November 2007 meeting, as this should be expected to direct more organs to children in the long run, and will look forward to reviewing the modeling data. This issue will be discussed further in a Joint Subcommittee in 2008.

1b. Liver and Intestinal Organ Allocation Policy Review

Liver-Intestine Working Group Update In July 2007, Dr. Simon Horslen, the Liver-Intestine Working Group Chair, provided members with a brief update regarding the latest round of data that were reviewed, and preliminary recommendations for policy modifications that are expected to be released for public comment in February 2008 (**Exhibit J**). The Committee voted unanimously (17-0-0) to share the Working Group recommendations with the Liver Committee in November. In addition to this, the Committee will request that several members be included in the Liver and Intestinal Organ Transplantation Committee's Split Liver Subcommittee for further discussion on how to best incentivize technical variants that will ultimately benefit both pediatric and adult candidates.

Dr. Horslen provided the full Committee with an overview of Working Group progress made and data reviewed during its October 19, 2007, conference call during the November 2007, meeting (**Exhibit K**). A liver proposal is under development based on the Working Group's progress over

the last 18 months. Drs. Horslen and Sweet shared data and an overview of the Committee's plan for a public comment proposal with the full Liver and Intestinal Organ Transplantation Committee during its November 28, 2007, meeting.

The proposal will specifically address allocation of young pediatric donor livers (defined here as age 0-10 yrs). In 2005, modifications to allocation policy refined (1) pediatric Status 1 definitions into 1A and 1B and (2) regional sharing of pediatric donor livers. The intent of the policy modification is to build upon these improvements, creating a new allocation algorithm specifically for young pediatric donor livers that will allow for broader sharing to the sickest pediatric candidates on a national level. The 0-10 age group was specifically chosen because, historically, only 1% of all livers from donors less than 12 years of age are transplanted into adults. As a result, the Pediatric Committee agreed that extending offers nationally to all 0-11 year-old Status 1A pediatric liver only candidates before making local adult Status 1A offers for this specific donor age group should be expected to reduce waiting list mortality for the children at highest risk of death without negatively impacting adult candidates. Upon completion of local and regional adult Status 1A offers, the Committees propose that pediatric Status 1B offers then be made locally and regionally before returning to the current algorithm currently used for pediatric donors.

Three different algorithms were tentatively drawn up as options for consideration (**Exhibit L**). The Working Group will meet with representatives from the Liver and Intestinal Organ Transplantation Committee as a Joint Subcommittee to review this proposal and suggest the idea of releasing these modifications as a joint effort between the committees to reflect consensus on changing the current allocation algorithm to better serve these young children. This meeting is anticipated in December 2008. The Committee also recognized that it will need to address how these changes will integrate with current liver-intestine policy for pediatric donors.

Members noted that split livers will be a topic of continued interest to the Working Group, but that any ideas for incentivizing this process will not be bundled into upcoming policy changes, but rather looked at as a separate initiative.

The Committee voted unanimously (19 yes, 0 no, 0 abstentions) to authorize the Liver-Intestine Working Group to finalize this proposal on its behalf for the upcoming February public comment cycle.

Evaluation of MELD/PELD Share 15 and Regional Sharing of Pediatric Liver Donor Policies
The Committee has been monitoring the liver MELD/PELD (M/P) Share 15 policy (implemented on January 12, 2005) and the liver policy changes involving the refinement of Status 1 definitions into 1A and 1B, and the regional sharing of pediatric liver (implemented on August 24, 2005). Specifically, the Committee was presented with quarterly update of wait list mortality and the number of pediatric transplants (all and split) by M/P score before and after the implementation of these policies, as well as whether adult waiting list mortality rates were affected by the 8/24/05 policy changes.

During the July 2007 meeting, Dr. Cherikh presented wait list death rates data (**Exhibit M**) that suggested the following:

- Increase in death rates in higher M/P score category (15+, 15-24, 25+) for the 0-11 age group, although it did not reach statistical significance.
- No increase in death rates in any score category for the 12-17 age group.
- No increase in death rates in any status 1 category for the 0-11 and 12-17 age groups.

The transplant data suggested the following:

- Percent of recipients transplanted in M/P score 15+ seemed to increase for the 0-11 and 12-17 age groups.
- Percent of transplants in M/P score <15 seemed to decrease for the 12-17 age group.
- Despite small numbers, percent of split liver transplants done in the 0-11 recipients from adolescent or adult donors seemed to increase

After review, the Committee requested updated reports every six months on the following additional points:

- Crude relative risk of death on the waiting list (instead of wait list death rates) for pediatric candidates aged 0-11 and 12-17, stratified by status or M/P score as well as overall wait list death rates. Tabulate causes of death for pediatric candidates who died on the waiting list.
- Number of liver transplants by donor age (0-11, 12-17, 18+), recipient age (0-11, 12-17, 18+), and status at transplants.
- Number and percent of split liver transplants relative to all liver transplants, stratified by donor age (0-11, 12-17, 18+), and recipient age (0-11, 12-17, 18+).

These reports will be stratified in three groups:

- Prior to MELD/PELD Share 15 policy implementation;
- After MELD/PELD Share 15 policy implementation but prior to the 8-24-05 policy implementation; and
- After the 8-24-05 policy implementation.

Recalculating PELD Coefficients The Committee reviewed updated SRTR data outlining the potential benefits of recalculating PELD coefficients during its July 2007 meeting (**Exhibit N**). This latest iteration does note that children would gain several PELD points under the updated PELD system, but the Committee is cognizant of the significant workload already placed on the IT department. As a result, this project is not a priority with the Committee at this time.

Outcomes of Pediatric Liver and Kidney Transplants from DCD Donors In November 2007, Committee members reviewed Kaplan-Meier graft and patient survival of pediatric recipients of DCD donors, originally requested by the Liver-Intestine Working Group (**Exhibit O**).

Between 1995 and 2004, there were 31 pediatric recipients who received DCD donor kidneys, with nearly 60% of these transplants occurring between 2002 and 2005. Two-thirds of these transplant recipients were adolescents.

Between 1995 and 2004, there were 14 pediatric recipients who received DCD donor livers, with 50% of these transplants occurring between 2003 and 2004. These transplants were nearly evenly divided between children and adolescents.

Graft and patient survival rates between brain dead and DCD kidney transplants were not statistically different; however, the rates were somewhat lower for transplant from DCD donors. At one year, graft survival rates for DCD donor transplants were slightly lower for DCD donors, 87.1% as compared to 90% of brain dead donors. Similar data for liver transplants showed that graft and patient survival rates between brain dead and DCD liver transplants were not statistically significantly different, but the rates were somewhat lower for transplants from brain

dead donors. At one year, the graft survival rate for DCD donor livers was 92.9% as compared to 78.2% for brain dead donors.

Members agreed that, though the numbers are small, they are encouraging and that DCD should be reviewed more closely. A member suggested the importance of sharing this information with the pediatric intensivists community, as we work to build relationships with this group to increase the opportunity for donation. It was suggested that an abstract for a pediatric critical care meeting or journal be put together to share this information.

Liver Regional Review Boards – Anecdotal Concerns During its November 2007 meeting, the Committee discussed an anecdotal concern raised during the September 2007 Board of Directors meeting that suggested pediatric candidates in some regions may not be treated fairly when cases are reviewed by Regional Review Boards. The Committee reviewed data (**Exhibit P**), but did not see any clear areas of concerns. Overall, children seemed to fare better than adults in the review process. Regional results vary from 4.5% to 25%. UNOS Staff will talk with the Liver Committee liaison to determine if a Joint Subcommittee should be formed to review this issue more closely.

A crossover member noted that the Liver and Intestinal Organ Transplantation Committee is considering a National Review Board as an option, with a pediatric component. This was seen as an option to equalize the review process across the country. It was pointed out that as this Committee pursues national sharing of organs, it is critical that regional bias not affect this sharing when consider cases. A Subcommittee was formed in the Liver and Intestinal Transplantation Committee. It was suggested that the Pediatric Committee provide some representation on this group as the idea is explored.

Policy Oversight Committee Review of Policy 3, Appendix B (Indications of Liver Transplantation in Children) During its review of all liver policy, the Policy Oversight Committee (POC) suggested that Appendix B (**Exhibit Q**) is now obsolete. The POC recommended that the appendix be deleted and requested input from the Pediatric and Liver-Intestine Committees. After a brief discussion, the Committee voted unanimously (18 yes, 0 no, 0 abstentions) to support the POC's suggestion of deleting this appendix from OPTN/UNOS policy during the November 2007 meeting.

1c. Kidney Allocation Policy Review

Kidney-Pancreas Working Group Update In July 2007, the Kidney Working Group Chair, Dr. Sharon Bartosh, provided members with a brief update regarding the latest round of data that were reviewed (**Exhibit R**), and preliminary recommendations for policy modifications that will be shared with the Kidney Committee as it continues to consider changes to the current allocation system. The Committee voted unanimously (17-0-0) to share the Working Group recommendations with the Kidney Committee during its December meeting.

Dr. Bartosh provided the full Committee with an overview of progress made and data reviewed during its October 15, 2007, conference call during the Committee's November 2007 meeting in Chicago. In keeping with the guidelines set forth during the Pediatric Summit, this group has continued its focus on:

- Determining which groups of pediatric candidates are dying on the kidney wait list. Data indicates that 30% of deaths were noted as highly sensitized candidates with PRA >80, 41% were re-transplanted, 35% were inactive at the time of death, and 41% received no offers while waiting for transplant.

- The impact of Share 35, giving children priority for donors <35 years of age, on sensitized children and the number of living donor transplants. Also
- Improving utilization of pediatric donors and identifying treatable factors that may help avoid discarding organs.
- Considering the point at which re-transplant may be futile more closely
- Allocation policies and practices that potentially disadvantage kids (i.e. <35 year-old donor kidneys offered out for multi organ transplant such as adult combined kidney-pancreas or liver-kidney before pediatric offers).

Sensitized Pediatric Candidates and Kidney Allocation In November, concerns were discussed that upon implementation of Share 35 policy (which offers pediatric candidates priority for kidneys from deceased donors <35 years of age), highly sensitized children were intermingled with adults waiting for transplant, when several members of the pediatric community felt that these children should receive offers before the highly sensitized adults on the match run. A brief call was held on October 10, 2007, with the Chairs from this Committee and the Pediatric Committee. Dr. Ruth McDonald, Ex Officio and current Kidney Committee member, also attended. Participants reviewed data comparing time to transplant for sensitized candidates pre- and post-Share 35 policy implementation (**Exhibit S**).

Committee members questioned whether this issue should be considered now or whether the community should wait until the new kidney allocation system proposal was drafted to see if this concern would be resolved. During the Working Group meeting that followed the October 10th call with Drs. Stock and McDonald, members noted that they would prefer to address this issue now. The topic will be discussed during an upcoming Kidney Committee meeting to try and make headway on this concerning issue.

Evaluation of Modification to Policy 3.5.11.5 on Pediatric Priority for Kidneys from Deceased Donors Under Age 35 The Committee continued evaluation of modifications to OPTN/UNOS Policy 3.5.11.5 on pediatric priority for kidneys from deceased donors <35 years of age in July. Data showed a trend towards an increasing number of deceased donor kidney transplants performed in pediatric recipients, especially from donors aged <35, after the policy was implemented (**Exhibit T**). However, the number of living donor transplants in pediatrics and the number of pediatric transplants with higher HLA mismatch level appeared to increase after the policy was implemented. Preliminary data on survival showed that graft and patient survival within one year of transplant did not seem to be adversely affected, but the Committee is concerned about the longer-term survival.

Members agreed that a decline in living donation seen since implementation was concerning, and that pediatric candidates receive a greater benefit from receiving living donor kidneys. The Working Group will continue to monitor this trend and consider ways to incentivize living donation and leave more deceased donor kidneys for those candidates without the option living donor kidney transplant.

The Committee will review updated reports in approximately 6 months on the number of transplants by recipient and donor age; time to transplant; characteristics of recipients (such as PRA level, HLA mismatch level, ethnicity); and post-transplant outcomes (creatinine level, incidence of delayed graft function, acute rejection rate and survival) before and after the policy implementation. Additionally, the Committee would like to know if pediatrics candidates were receiving and accepting offers from donors ≥ 35 years.

The Committee requested that the SRTR utilize the existing Center Specific post-transplant survival model for kidney to compare the expected three- and five-year graft survival of the pediatric patients transplanted during the pre- and post-share 35 policy. The goal is to estimate (based on historical data) how much lower the three- and five-year graft survival is going to be with the higher percentage of deceased donors and less well matched kidneys since the new policy went into place. This data will be reviewed during the November 2007 meeting.

Evaluation of Share 35 Policy – Preference for Kidneys from Pediatric Donors Age < 35 Years

In November, the SRTR provided members with a comparison of the expected 3 and 5 year graft survival of pediatric recipients transplant during the pre- and post- Share 35 policy using the existing SRTR center-specific post-transplant survival (**Exhibit U**). The Committee was interested in studying if graft survival was worse with the higher percentage of deceased donors and less well matched kidneys since Share 35 was implemented. Results indicated that there were 23% less living donor transplants and a 59% increase in deceased donor transplants since policy implementation. This increase was attributed to shorter wait times in the post-policy period, which was anticipated to lead to more deceased donor transplants (a bolus effect) until a new steady state is reached. The decrease in wait time does not appear to change the living donor transplant rate. There has not been enough time for reliable reporting of graft failures, especially in living donor recipients. Given the change in absolute percentages of living and deceased donor transplants, it appears that the overall graft failure rate among all recipients post-policy will be roughly 12% higher.

Waiting Times for Pediatric Candidates after Kidney Share 35 Policy; and Re-transplant Rates in Pediatric Patients with FSGS, MPGN and HUS Members requested data to review wait times for pediatric candidates with intermediate PRA levels or blood groups B before and after the Share 35 policy change, presented as percent of transplant within three, six and twelve months. This information was stratified by PRA level and ABO for pediatric and adult candidates.

Results reviewed in November (**Exhibit V**) indicated that the probability of receiving a deceased donor transplant for Type B pediatric candidates seemed to increase after this policy change for all age groups. Overall, the probability of receiving a deceased donor transplant increased for all blood types in children post-policy change, while the probability of an adult receiving a deceased donor transplant did not increase regardless of blood type.

The number of pediatric candidates aged 0-5 and 6-10 with intermediate PRA was too small to determine probability of transplant. The less than ten candidates in this group were not included. Adolescents with intermediate PRA (20-79) experienced an increase in the probability of receiving a transplant within 3 months as compared to the post-policy period. Adolescents with high PRA (80+) say an increased probability of transplant within 3, 6, and 12 months of transplant after the Share 35 policy change.

Members also reviewed data on the number of re-transplants in pediatric recipients with Focal Glomerular Sclerosis (FGS), Mesangio-Capillary 1 Glomerulonephritis and Mesangio-Capillary 2 Glomerulonephritis (MPGN) and Hemolytic Uremic Syndrome (HUS). During the 1995-2005 study period, there were 860 FGS cases, 177 HUS cases and 67 MPGN cases. Probability of re-transplant within 5 years was 8% for FSGS, 7% for HUS and 9% for MPGN, with re-transplant of MPGN2 higher than that of MPGN1.

The Committee requested additional data on recipients of first kidney alone transplant during 2000-2005. For the next meeting overall re-transplant rates for all pediatrics and adults less than 65 years of age will be compared with re-transplant rates for pediatrics with FSGS, MPGN, and

HUS; summarize causes of graft loss. The rate of returning to dialysis as opposed to re-transplant will also be calculated since this may be more informative than re-transplant rate alone

Evaluation of Modification to OPTN/UNOS Policy on Pediatric Priority for Kidneys from Deceased Donors < Age 35: Number of Transplants Before and After the Policy Implementation

The Committee continued its bi-annual review of the number of transplants by recipients and donor age; time to transplant; characteristics of recipients (including PRA level, HLA mismatch, ethnicity); and post-transplant outcomes before and after policy implementation in November (**Exhibit W**). The Committee requested the number of offers from and accepted from donors ≥ 35 years of age.

Deceased Donor Pancreas after Living Donor Kidney vs. Simultaneous Kidney-Pancreas Transplant; and Post-Transplant Outcomes for Pediatric Combined Kidney-Liver vs. Liver Alone Transplant and Kidney-Heart vs. Heart Alone Transplant During the November 2007, meeting, Dr. Wida Cherikh, UNOS Senior Biostatistician, presented data detailing: (1) the trend over time of the number of deceased donor pancreas transplants that had already received a previous living donor kidney transplant (PAK) to determine if more centers are performing PAK transplants than simultaneous kidney-pancreas (SKP) transplants; (2) post-transplant outcomes for pediatric recipients of combined kidney-liver versus liver alone transplant; and (3) post-transplant outcomes for pediatric recipients of combined kidney-heart versus heart alone transplant (**Exhibit X**).

There has been an increase of PAKs over time. While the percentage of SKPs seems to have decreased, the actual number of transplants has increased dramatically over time. As a result, concerns have been raised from the pediatric transplant community that they believe they are losing a number of <35 year-old donor kidneys to adult SKPs, which is allowed under current kidney allocation policy. A member noted that outcomes for SPK are generally better than PAK. Wait time is also shorter for SPKs in some regions. As a result, some adults with the potential for a living donor kidney option are sometimes counseled to list for an SPK rather than wait for an isolated pancreas after receiving a living donor kidney. OPO representatives suggested that the pressure to meet the Collaborative's organ per donor metric may move to place a SPK, rather than try to place the isolated pancreas. Members recognized that the ideal SPK is from the same donor as the ideal kidney donor for pediatric candidates, indicating that there will always be pushback from the adult community to maintain access to these organs.

A review of patient and liver graft survival rates for pediatric recipients of deceased donor combined kidney-liver and liver alone transplants indicated that overall patient survival rates between these two groups were comparable. Overall liver graft survival rates for combined liver-kidney seemed higher than those for liver alone transplants, though the difference was not statistically significant. Members questioned if there is a group of candidates that benefit from receiving a combined transplant rather than waiting for kidney function to recover after liver transplant when appropriate. The data did not answer this question. How the increasing trend of allocating liver-kidney to adult end stage candidates affecting children will be considered by the Working Group in an upcoming call. Several members agreed that there is little data for adults or children to determine which patients regain kidney function after liver transplant, and that this is an area that needs to be studied. Unfortunately, if one kidney goes to SPK and one goes with a liver, then there are a limited number of <35 kidneys for transplant in children. A member questioned if it would be prudent to offer expedited kidney transplant to liver recipients whose renal function does not return after six months. The Liver and Intestinal Organ Transplantation Committee was said to be developing guidelines that specify cases where it is appropriate to

transplant a combined liver-kidney. These include chronic renal failure with GFR<30 and acute candidates that have been on dialysis for 6 weeks or more.

Patient survival rates for combined kidney-heart and heart alone transplant were comparable. It was acknowledged that there are a relatively small number of these transplants completed each year as compared to liver-kidney and kidney-pancreas.

The Working Group requested additional data to determine how many of the <35 year old donor kidneys are allocated to children and to adults for SPK, combined renal-non renal transplant, zero antigen mismatch and how many are lost to paybacks. This data will also be considered by region. Ultimately, the Working Group hopes to work with the respective organ specific committees to develop criteria for multi-organ transplant that will help prevent <35 year-old donor kidneys from unnecessarily following other organs for transplant. Such criteria would ensure that pediatric candidates are not losing opportunity for transplant unnecessarily.

Organ Utilization by Donor Age The Committee reviewed data on organ utilization rates and a detailed disposition of organs not transplanted stratified by donor age (**Exhibit Y**) to get a clearer understanding about factors that lead to death on the pediatric kidney wait list in November 2007. Members reviewed the disposition for all organs by age group where:

- Consent was not requested,
- Consent was not obtained,
- Organ was not recovered,
- Organ recovered, but not for transplant,
- Organ recovered for transplant, but not transplanted, or
- Organ was transplanted.

Data indicated that there was certainly no sign of an excessive discard rate on donor kidneys from <35 year old donors offered preferentially to children.

Kidney Committee Progress Update Ms. Shandie Covington, Committee Liaison, and Dr. Mark Fox, crossover representative for these two Committees, provided members with a brief update regarding the Kidney Committee's progress on ongoing allocation policy development in July 2007 (**Exhibit Z**).

The Committee received another update in November on recent activity in the Kidney Transplantation Committee (**Exhibit AA**) as it continues to develop a concept proposal for a new kidney allocation system. A concept proposal document is anticipated in March 2008. The Committee will monitor this process closely, as it has still not seen anything concrete regarding how children will be treated in this new allocation system other than hearing that children will only receive offers for <35 year-old donors. A second Forum will be held to discuss plans for the new allocation system in February or March 2008.

The Committee requested that an integrated plan for pediatrics be presented for consideration prior to the expected March public comment. Staff will work to arrange a Joint Subcommittee to share this information.

The Committee will address its concerns regarding the upcoming kidney allocation proposal to the Kidney Committee during its December 3 meeting, and plans to form a Joint Subcommittee to discuss this topic in detail in January, as the Kidney Committee develops its concept proposal for public comment.

1d. Pancreas Allocation Policy Review

The Committee reviewed a memo requesting input on how to account for the pancreas in multi-visceral transplants from the Pancreas Transplantation Committee (**Exhibit BB**) during its November 2007, meeting. All organs are to be allocated to potential recipients appearing on a match run, but pancreas policy 3.2.7 requires that candidates registered for a pancreas must be diagnosed as a diabetic or have pancreatic deficiency. Should multi-organ candidates be listed on the pancreas match run if they need a pancreas only for technical reasons? A member noted that using a liver-intestine generally precludes the use of the pancreas. Likewise, the intestine is precluded in most cases of pancreas recovery. In transplanting a liver-bowel, the pancreas often remains intact to maintain the integrity of the liver-intestine allograft, and is then reduced after the graft is transplanted. In some cases, the OPO is charging for this pancreas, even though it is not used and would have more than likely been disposed of in the case of a liver-intestine transplant, but this practice varies widely across the country. Policy does not address this scenario in any way. Additionally, members agreed that you cannot always anticipate that the pancreas will be needed pre-recovery.

How does the Final Rule and OPTN/UNOS policy address an organ that is not transplanted to replace function, but rather to facilitate transplant of other organs? This will impact match runs and follow-up forms for the pancreas. Until this is addressed, these questions cannot be answered. HRSA and Collaborative performance goals for organs transplanted per donor could be affected by how these pancreata are categorized.

The Pediatric Committee believes that, until policy addresses this situation and it aligns with the Final Rule, compliance and follow-up implications cannot be addressed. Therefore, the Committee cannot support the proposed policy change as written. A response memo will be drafted to the Pancreas Transplantation Committee to convey this discussion.

2. Discussion of Living Donor Follow-up Requirements During the November 2007 meeting, members discussed their frustration with recent policy implementations requiring pediatric programs be responsible for living donor follow-up for any organs transplanted at their center. Dr. McDonald voiced her concerns regarding the follow up requirements during a recent Living Donor Committee meeting (**Exhibit CC**). For some pediatric transplant centers, organ procurement from adult living donors is done at an adult transplant facility and then the organ is transported to the pediatric facility. Members suggested that the adult center recovering the organ is in a much better position to provide follow-up on an adult donor than the pediatric center, which has never seen or treated the donor. A scenario where living donor paired exchanges or anonymous donation where the nephrectomy is completed at a different center was also suggested as a comparable scenario not necessarily involving a pediatric center. The Committee voiced frustration that short of developing formal contracts with recovering centers to manage follow-up, there was little they could do to mandate data collection for these donors. A scenario where recovery takes place at a hospital without a transplant program also presents unique challenges, as this hospital would not have access to or reminders of follow up forms as they are due. Two components were outlined: (1) pediatric programs must accept responsibility and protect themselves by appropriately contracting adult programs to be responsible for this follow up; and (2) adult programs should not be absolved of their responsibility if they fail to meet these contract requirements as outlined. It was noted that pediatric centers are not the best resource for adult follow-up, and this is not an insignificant concern when considering what is best for these living

donors. An additional suggestion was to change living donor registration to begin prior to transplant, routing follow up to the recovering center rather than the transplanting center.

The Committee agreed to request a Joint Subcommittee with representatives from the Living Donor and Membership and Professional Standards Committees to discuss these concerns and determine the possibility of alternate requirements for pediatric programs or policy language that is mutually acceptable to all parties. Drs. Anthony Savo, Patrick Healey and Ruth McDonald were appointed for this Joint Subcommittee.

3. Joint Pediatric-OPO Subcommittee Concerns related to the lack of best practices for administering pre-recovery medications and donor management led to the formation of a joint subcommittee with the OPO Committee in 2006. Specifically, some intestinal programs utilize ATG in donors prior to procurement of intestines. Thoracic teams recovering organs from these donors have expressed concerns about the impact of such infusions on other donor organs. This raised issues regarding what drugs should be administered in an effort to manage donors and what blood draws happen prior to procurement. Due to a number of scheduling conflicts, this group has not yet convened, and several of the original members have since rolled off the Committees. During the November 2007 meeting, Drs. Bill Pietra, Anthony Savo and Stuart Sweet were appointed to represent the Pediatric Committee on a conference call to be set up in early 2008 to discuss this issue. New appointments were also made during a recent OPO Committee meeting.
4. Review of Policies and Bylaws Issued for Public Comment
 - 4a. Proposals Issued on June 15, 2007 The Committee reviewed the four proposals out for public comment, and provided the following feedback during its July 2007 meeting:
 1. *Request for Incorporating CPRA into an Existing Alternative System for Kidneys (Histocompatibility Committee)* After discussion, the Committee determined there was no specific pediatric issue requiring further comment.
 2. *Proposed Modifications to OPTN/UNOS Policy 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth (HPDGH), and Reporting of Potential Recipient Diseases or Medical Conditions, including Malignancies, of Donor Origin) (Operations Committee)* The Committee agreed with tightening screening requirements, but questioned the use of the word “potential,” noting that there is no definition of this term anywhere within the policy language to denote when a center should report a potential transmission – i.e. when the test is ordered and a physician is attempting to rule out concerns or upon receipt of results. The Committee requests clarifications regarding the use of the word “potential” in this instance if centers are to be held responsible for communicating this information at a specific time.

Additional concerns were raised regarding the requirement for consent. At what level should donor characteristics be disclosed to the recipient? Should this be specified? Requirement for consent is not clearly specified and perhaps inconsistent across these recommendations, seen only in policy 4.5 (Human Pituitary Derived Growth Hormone). Members, noting that the topic has been touched upon by CMS, questioned whether the Operations Committee has considered making this more clearly defined in OPTN/UNOS policy?

After discussion, the Committee voted unanimously in support of the proposal, but requested clarification regarding the intended meaning of “potential” in Policy 4.7 and consideration as to whether specifications for consent should be detailed within policy other than what is outlined for potential recipients of organs from donors that have received Human Pituitary Derived Growth Hormone. (Committee vote: 17-0-0)

3. *Proposed Modifications to OPTN/UNOS Policy 7.4 Submission of Organ-Specific Transplant Recipient Follow-up Forms. (Operations Committee)* Upon review, members agreed that the proposal does not justify the patient safety criteria for this additional data burden, if deaths are currently required to be reported within 14 days of center notification. Members considered the two day time requirement to be extreme, suggesting that the proposal does not demonstrate how the data will be used. If the purpose is to notify other recipients of the potential for transmission of a donor-derived disease, then a two day window is appropriate. If death occurs in the first year post-transplant due to other causes (i.e. car accident, fall, etc.) the time frame is too rigid. Members suggested that a more efficient approach should be developed using the suggested modifications to Policy 4.0 to capture deaths specifically related to donor-derived disease in a more expedited fashion. The Committee voted unanimously to oppose this proposal as written, citing the concerns outlined above. (Committee vote: 18-0-0)
 4. *Proposed Modifications to OPTN/UNOS Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer) (Organ Availability Committee)* After discussion, the Committee generally supports this recommendation, but is not optimistic that encouragement will change practice within all DSAs. It was noted that very few pediatric kidneys are pumped at this time. (Committee vote: 18-0-0)
- 4b. *Proposals Issued on July 13, 2007* The Committee reviewed the four proposals out for public comment, and provided the following feedback during its July 2007 meeting:
1. *Proposed Modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII,C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation (Membership and Professional Standards and Living Donor Committees)*

The Committee considered proposals #1 and #2 together and offered its comments on both below.

2. *Proposed Modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Living Donor Liver Transplants (Membership and Professional Standards and Living Donor Committees)* Upon review, a member noted that the proposals are meant to align OPTN/UNOS bylaws with CMS requirements. A member suggested that the word “independent” when used in Independent Donor Advocate (IDA) is controversial and not well understood in this context. Neither CMS nor UNOS has offered a specific definition, but it is assumed that, as referenced, it is implied that the IDA have no perceived conflict of interest in advocating for a donor. The Committee unanimously supports the modifications to the Bylaws and asks that the Living Donor Committee consider formalizing a definition for the term IDA. (Committee vote: 17-0-0)

Because these proposals were not released for public review until the day this meeting, the Committee opted to vote on the following proposals at a later date to allow themselves more time to read and consider them in greater detail. Members completed their review and discussion via email. A formal vote count was not taken, but opposition and support was counted by email replies and feedback submitted to the Chair, Vice-Chair and Liaison.

3. *Guidelines for the Medical Evaluation of Living Kidney Donors (Living Donor Committee)*
4. *Guidelines for the Consent of Living Donors (Living Donor Committee)*

After reviewing the proposal, members again cited concerns regarding the purpose of issuing clinical guidelines by UNOS as opposed to policy. The proposals are within the range of good practice but members noted that even though they are described as guidelines they may be read and treated (by patients and insurers) as standards of care. Additional concern noted that the specific detail within guidelines will not remain current, and will require frequent updating to comply with CMS and standard operating procedures. Members suggested a way of prescribing overarching concepts for good living donor evaluation and consent for all organ types and then documenting examples of individual center protocols which fulfill these concepts and are considered acceptable. The Living Donor Committee noted utilizing 16 center protocols and the AST recommendations to develop these guidelines. Members questioned whether utilizing these actual protocols and recommendations might prove more effective than the proposed guidelines themselves.

Several questions and comments were raised regarding specific sections of the proposal, including:

- Members noted that there is no language within the proposal outlining how to address adult living donors for pediatric recipients receiving treatment in freestanding pediatric hospitals. It was suggested that the adult program managing the adult's living donation procedure should be noted as specifically responsible for living donor follow-up, not the pediatric program.
- Item L (Donor Evaluation) Members disagreed with the requirement that appears to imply that centers would be responsible for providing donors with medical and/or disability insurance.
- Item M (Donor Evaluation) Members requested clarification on the requirement regarding valuable consideration. NOTA does allow assistance for travel and subsistence for living donors during evaluation and a specific period of post-transplant.
- Item N (Donor Evaluation) Members were concerned that this language may not be appropriate, suggesting that potential donors should be notified of all Medicare requirements not being met within their organ-specific program rather than the full transplant center. Other organ specific program outcomes are irrelevant to outcomes experienced by the living liver transplant program.
- Item O (Donor Evaluation) After reading this section, members requested clarification on what would be specifically expected of centers to "specify who is responsible for the cost of follow-up care."

The Committee was concerned that the Kidney Transplantation and the Liver and Intestinal Organ Transplantation Committees did not appear to be involved in

developing and drafting these guidelines. Based on the number of issues raised, the Committee did not support these proposals. (Committee vote: 10-2-0)

- 4c. Proposal Issued on September 28, 2007 The Committee reviewed the Membership and Professional Standards Committee's proposal for public comment during its November 2007 meeting and provided the following feedback:

Proposed Modification to the OPTN Bylaws, Appendix B, Transplant Hospitals; Section B. Survival Rates; and Section C "Inactive Membership Status"; and Attachment I, Section II, "Inactive Program Status"; and to the UNOS Bylaws, Attachment I, Section II "Inactive Program Status" and Attachment II, Section XIII, C, (10) "Survival Rates." The Committee reviewed the proposal during its November 29, 2007. Though this issue is not specifically pediatric in nature, the members agreed that an informal interview is beneficial to discuss cases where pediatric issues may not fall neatly into current Bylaws. After discussion, the Committee voted unanimously to support this proposal (18 yes, 0 no, 0 abstentions).

- 4d. Proposal Issued on November 12, 2007 The Committee reviewed the Living Donor Committee's Resource Document currently out for public comment, and provided the following feedback:

OPTN/UNOS Proposed Resource Document for the Medical Evaluation of Living Kidney Donors After discussion, the Pediatric Transplantation Committee determined there was no specific pediatric issue requiring further comment.

5. Discussion Regarding CMS Volume Requirements for Approval to Transplant Young Adults in Pediatric Centers Members reviewed a letter drafted by Dr. Sweet (**Exhibit DD**) to CMS detailing his personal concerns regarding new Conditions of Participation (COPs) that include specific volume requirements for adult transplants that are performed in pediatric transplant centers during the November 29, 2007, meeting. Review of OPTN data suggested that no pediatric center would be able to meet the adult transplant volume requirements outlined within the COP for re-approval. A review of 18-25 year-olds transplanted in adult programs (for all organ specialties) indicated that only a small number of kidney programs met the requirement of 10 transplants per year in this age group.

After discussing the letter, the Committee agreed that it is potentially detrimental to adult transplant candidates and recipients requesting treatment at pediatric centers to enforce such a condition for re-approval. Such requirements may negatively impact young adults by forcing them to transition to adult care prematurely, but could also be expected to disadvantage adults with conditions such as congenital heart disease. Many adult transplant programs refuse to list such candidates due to the high risks involved and instead refer them to pediatric programs that have more experience in treating candidates with this diagnosis. Members pointed out that CMS outlines its understanding about the importance of providing continuity of care to young adults within *Conditions of Participation: Pediatric Transplants (Proposed §482.76)*, yet the volume requirement for re-approval stands in direct conflict with this statement.

After discussion, members voted unanimously (20 yes, 0 no, 0 abstentions) to send a letter from the Committee on behalf of the pediatric transplant community that (1) supports concerns raised in the Chair's letter and (2) requests that CMS consider modifications to the COP that will allow centers performing 50% or more of their total number transplants on pediatric candidates to be exempt from volume requirements for pediatric and adult transplants for both initial approval and re-approval. Members agreed that such a change will better serve candidates of all ages receiving care at freestanding pediatric transplant programs.

This letter will be reviewed by the Executive Committee during its December 18, 2007 teleconference before it is submitted to CMS.

The letter was approved by the Executive Committee during its December 18, 2007, conference call. CMS reversed its stance on the same day that the Executive Committee met. The letter was sent with a follow-up memo to allow the Committee to go on record with its concerns (Exhibit EE**).*

6. Effects of Hormonal Resuscitation on Organ Utilization in Pediatric Donors Dr. Cherikh provided the Committee with a brief overview (**Exhibit FF**) of recent research regarding the effects of using hormonal resuscitation in pediatric donors on organ utilizations during the Committee's July 2007 meeting. This information was also shared during the Pediatric Summit in March 2007.
7. Update Regarding Actions from Recent Board of Directors Meetings The Committee discussed actions from the June 2007 Board of Directors meeting in July 2007. Of specific interest to this committee were the Board approved modifications to the pediatric data collection worksheets. These changes are expected to be implemented on September 1, 2007. Additionally, the Committee discussed the approved modifications to allocating organs from brain dead donors who convert to deceased donor status.

The Committee discussed actions from the September 2007 Board of Directors meeting during its November 2007 meeting. Of specific interest to this committee were: (1) discussions regarding a white paper underway from the OPTN/UNOS Ethics Committee and whether this paper should include any references to pediatric allocation; and (2) new data regarding turndowns and exhausted match runs using the new DonorNet electronic offer system. The Committee will review data to determine if expanding to national offers for pediatric donor organs will, in fact, be expected to increase allocation and ultimately reduce death on the pediatric wait list.

8. Update on OPTN/UNOS Strategic Plan The Committee reviewed its current charge of reducing death on the pediatric wait list in relation to specific challenges outlined in the Strategic Plan during its November 2007 meeting (**Exhibit GG**). The Committee's continued work will focus predominantly on three challenges: (1) donor shortage, (2) changing allocation principles, and (3) reducing variation in access to transplantation. The Committee's focus on defining an optimum environment for pediatric transplant through the identification of characteristics of successful programs also addresses challenges (1) and (3).
9. Update on HHS Program Goals In July 2007, the Committee was provided an update on the HHS Program Goals, including a brief overview of their intent and history of these goals for new Committee members (**Exhibit HH**). The purpose of these goals is to increase the number of deceased donors, the average number of organs transplanted from deceased donors, and the total number of deceased donor organs transplanted. Although the goals for organs transplanted and DCD donors were not met for 2006, there continues to be excellent performance in procuring non-DCD donors. The OPTN will continue with projections and focus on actual 2006 results at the regional/DSA level to help identify trends
10. Introduction of New Committee Members and Brief Orientation Drs. Sweet and Horslen, Committee Chair and Vice-Chair, welcomed new members to the Committee in July 2007. Ms. Covington provided a brief presentation regarding member roles and functions, while Dr. Sweet then detailed the Committee's recent activities related to its charge to decrease pediatric wait list death. Members were also provided with an overview of data and information available to them (and the public) on the UNOS, OPTN and SRTR websites.

11. Review of Critical Committee Information Support staff for the Pediatric Committee, including the Liaison, Research and IT staff liaisons, SRTR and HRSA representatives and Travel coordinators were reiterated as contacts when assistance is required during the November 2007, meeting. The role of members serving as regional representatives was also outlined again for clarification, noting the importance of reporting at all regional meetings and serving as a conduit of information both to and from their respective regions. Additionally, a reminder was offered that HRSA and UNOS would like to be notified if members are contacted by the media for comments or interviews. All were requested to notify the Committee Liaison, who can arrange for speaking points and other assistance if desired. A phone/pager number and email address was offered to members in addition to the Liaison's contact information. This information was also distributed to members by email after the meeting.

PEDIATRIC COMMITTEE		MONTH	JULY	NOVEMBER
		DAY	12	29
		FORMAT (select)	In Person	In Person
NAME	POSITION			
Stuart Sweet MD	Chair		X	X
Simon Horslen MB ChB	Vice Chair		X	X
Michael Chobanian MD	Region 1 Rep.		X	X
Anthony Savo MD	Region 2 Rep.		X	X
Ian Carmody MD	Region 3 Rep.			x (by phone)
Anthony Sebastian MD	Region 4 Rep.		X	x (by phone)
Christine Mudge RN, MS, CNS/PNPc	Region 5 Rep.		X	X
Patrick Healey MD	Region 6 Rep.			X
Sharon Bartosh MD	Region 7 Rep.		X	X
Ross Shepherd MD	Region 8 Rep.		X	
Steven Lobritto MD	Region 9 Rep.		x (by phone)	X
Joanne Dupuis RN	Region 10 Rep.		x (by phone)	X
Debra Dodd MD	Region 11 Rep.		x	
Estella Alonso MD	At Large		x	X
Kathie Collins RN,CCTC	At Large		x	X
Carol Conrad MD	At Large		x	x (by phone)
Sharon DiSano MS,ARNP,CCTC	At Large		x	X
Susan Dunn MBA,RN, BSN	At Large			X
Mark Fox MD, PhD	At Large		x	X
Heung Bae Kim MD	At Large		x	X
Robert Mazor M.D.	At Large			X
Victor Morell MD	At Large			
Amy Palermo	At Large			
Biagio Pietra MD	At Large		x	X
Elizabeth Roach RN, BSN	At Large		x	X
Elizabeth Ortiz-Rios MD, MPH	Ex Officio		x (by phone)	X
Monica Lin, PhD	Ex Officio			X
Jade Perdue MPA	Ex Officio		x	
Mary Guidinger MS	SRTR Liaison		x (by phone)	
William Harmon MD	SRTR Liaison		x	X
John Magee MD	SRTR Liaison		x (by phone)	X
Kate Meyer MS	SRTR Liaison			X
Jeff Moore MS	SRTR Liaison		x	x (by phone)
Shandie Covington BS	Committee Liaison		x	X
Wida Cherikh PhD	Support Staff		x	X
Karl McCleary PhD, MPH	Director		x	
John Lombardi	Support Staff		x	
Jennifer Mekolichick	Support Staff		x	
Leann Harris	Support Staff			X
Ruth McDonald, MD	Guest			x (by phone)