

**Interim Report of the OPTN/UNOS Pediatric Transplantation Committee
November 9, 2006
Convened by Teleconference and Live Meeting®**

**Stuart C. Sweet, M.D., PhD, Chair
Simon Horslen, M.D., Vice-Chair**

Old Business

Review of Proposals Addressed by the Board, September 20, 2006.

Dr. Stuart Sweet provided members with a brief account of actions take by the Board of Directors on September 20, 2006. He reported the approval of this Committee's proposal to modify OPTN/UNOS Policy 3.7.8 (ABO Testing for Heart Allocation), noting that implementation dates will be set at a later time as program priorities are assigned. He encouraged members to review the Executive Summary provided with meeting materials.

Review of the HHS Program Goals Update.

Due to the abbreviated agenda for this teleconference, Dr. Sweet requested members to independently consider the updated slides provided as part of the meeting materials CD showing progress toward meeting HRSA's Program Goals.

Update Regarding Mandatory DCD Protocols.

The Pediatric Committee continued its discussion regarding the January 1, 2007, implementation of the revised JCAHO organ procurement and donation standard as well as related modifications proposed by the OPO Committee to Appendix B of the OPTN Bylaws that require hospitals to develop and then comply with a protocol regarding donation after cardiac death (DCD). Members reviewed a presentation outlining one free-standing pediatric center's experience in developing a DCD protocol over the last year. A letter sent to the Pediatric Committee outlining concerns related to the OPO Committee's proposal was also considered. There is concern within at least some segments of the pediatric intensivist community, which have not embraced these protocols as part of end of life care.

After hearing Dr. Patrick Healey recount his center's challenges in implementing this protocol during the public comment review call held on October 3, 2006, it was suggested that pediatric programs in general may have more difficulty in influencing the necessary hospital leadership to put such protocols into place. After consideration, the Committee members participating in this call supported the proposal (5-0-0), but recommended the OPO Committee provide assistance, educational materials and example protocols from pediatric centers that already have protocols in place to help facilitate this process. The Pediatric Committee also requested information on the number of pediatric centers that now have protocols in place, and planned to discuss this further during its November 9, 2006, meeting. Mr. Charles Alexander, RN, MSN, OPO Committee Chair, and Dr. Jeffrey Punch, a MPSC member who participated in the Joint Working Group that developed the proposal, participated in this Committee's November 9, conference call to provide insight into the expectations of this proposal and answer any related questions.

Dr. Healey shared further details regarding his center's experiences in a free-standing children's hospital developing a pediatric DCD protocol to the Committee with a brief slide presentation during the teleconference (Exhibit A). He emphasized the importance of addressing concerns

from the intensivists community, where endorsement of this concept is essential. It was stressed that transparency of the process is very important, especially considering that most ICUs have their own processes for end of life care and withdrawal of support that may require adjustment to accommodate some of the standard DCD procedures. Dr. Healey recognized impediments to DCD to include:

- Hospital: Lack of protocols, or real interest
Physician and staff resistance
- OPO: Limited financial and staff resources
for outreach, education and technology
- Organs: Concerns about the quality of DCD organs
and utilization
- Ethics: Medical interventions
Termination of life-sustaining treatment
Determination of death

Dr. Healey did question whether pediatric DCD donor organs were being utilized for pediatric recipients, citing the data below:

2003 data	Total	<18 years of age
DCD donors	271	28
DCD kidney transplant recipients	394	9
DCD liver transplant recipients	114	5

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This data indicates that most pediatric DCD organs are utilized for adult recipients. He also recognized that challenges specific to pediatric hospitals include: (1) low donor volumes, (2) low volume transplant, (3) may be both donor hospital and transplant center with low volumes, and (4) a best practice model has not yet been determined for DCD in children. He noted that this must first be looked at as an end of life issue, recognizing that if parents want to donate, it is a hospital's responsibility to find a way to meet the request. Healey reported that his center will have it protocol in place for the January 1, 2007, deadline, but recognized that it has taken approximately a year to complete the process.

The Committee then reviewed a recent letter from a pediatric center reporting its concerns regarding the upcoming January 1, 2007 deadline for such protocols to be in place for transplant centers (Exhibit B). Co-Chairs of this center's Task Force on DCD suggested that there are unique differences for pediatric patients and DCD that it feels have not been, and requested a delay in requiring such protocols for pediatric institutions. It was suggested a national consensus conference on pediatric DCD be convened in the near future, where the by-law modifications might be reconsidered on the basis of evidence and opinion gathered at the conference.

A member noted his program has worked through a process similar to that shared by Dr. Healey, but has still not come to a consensus. Two issues continue to remain outstanding:

1. An ethical issue of whether a parent's or parents' decision to pursue DCD donation is in the best interest of the child. In the case of DCD, a child is still alive, unlike a standard criteria donor that is brain dead. Some see DCD as withdrawing care to the pediatric patient. Some ethicists participating in this center's working group could not resolve these concerns.

2. The position of the pediatric intensivists must also be considered. Though it may be an emotional response, many oppose the DCD donation process and an intrusion into a carefully developed process.

He related that discussion became very polarized when presenting a proposed DCD plan to the hospital's Board of Directors. He suggested this Committee review the DCD requirements and consider their place in the pediatric community.

Dr. Jeffrey Punch noted that pediatric DCD cases have been some of the most gratifying in his opinion, with families being most appreciative of an opportunity to bring hope to an always difficult situation. He suggested he sees no issues separating the pediatric and adult DCD process. Disagreeing with the ethical arguments noted in the letter, Punch suggested there should be no downside to DCD if you believe that it is ethical to withdraw care, a part of natural end of life care.

An intensivist on the Pediatric Committee recognized that DCD is an emotional issue, especially when dealing with pediatric death. He sees the response within this community as possible reaction against the upcoming requirements as mandatory. He noted consensus statements from the Institute of Medicine and the Society of Critical Care Medicine (SCCM) are frequently referenced within centers that are working to develop these protocols. It is important to recognize these statements are not based on pediatric medicine, as no best practice models for DCD have been developed for children. Members also voiced concerns that there are differences between pediatric and adult DCD, questioning whether measures to define death are the same for adults and children. It was noted that all current references are based on adults. After discussion, it was suggested this Committee make a recommendation regarding these practices, agreeing with the letter's recommendation of a pediatric conference on pediatric DCD to consider these issues in greater detail.

Members suggested that it should be this Committee's role to take a lead in determining the a position for pediatric organ donation by outlining components of a best practice model for DCD in children, noting that the other professional societies would look to the transplant community for guidance. Dr. Sweet agreed, noting this Committee should support its goals to ensure that every child has his/her best opportunity for transplant and having a good post-transplant outcome by recognizing that DCD is in the best interest of the pediatric community- whether these organs go to a child or to an adult that may have been competing on the wait list with a child for an organ. Using this as a framework, he recognized the importance of partnering with other organizations who are taking the lead in moving DCD forward. As a result, he recommended that the Committee support the upcoming DCD protocol requirements, recognizing that the pediatric transplant community tends to respond more slowly. It was suggested that programs unable to meet the January 1, 2007, deadline submit documentation detailing where they are in the process of meeting these requirements, as well as an interim plan for responding to families who wish to pursue DCD before such protocols are in place. It was noted that the JCAHO standard requires a policy be in place, not that DCD recoveries actually be performed.

As a result of these discussions, the Pediatric Committee will address its concerns to the Board of Directors during its December 2006 meeting with the following resolution:

**** RESOLVED**, that the Pediatric Transplantation Committee reinforces its support for the DCD protocol initiative, but requests that the Board and Membership and Professional Standards Committee recognize the unique challenges faced by pediatric hospitals in establishing these protocols. Therefore, the Committee requests that enforcement of the

policy for transplant hospitals treating primarily pediatric patients be deferred as long as the hospital demonstrates ongoing progress toward putting pediatric DCD protocols in place.

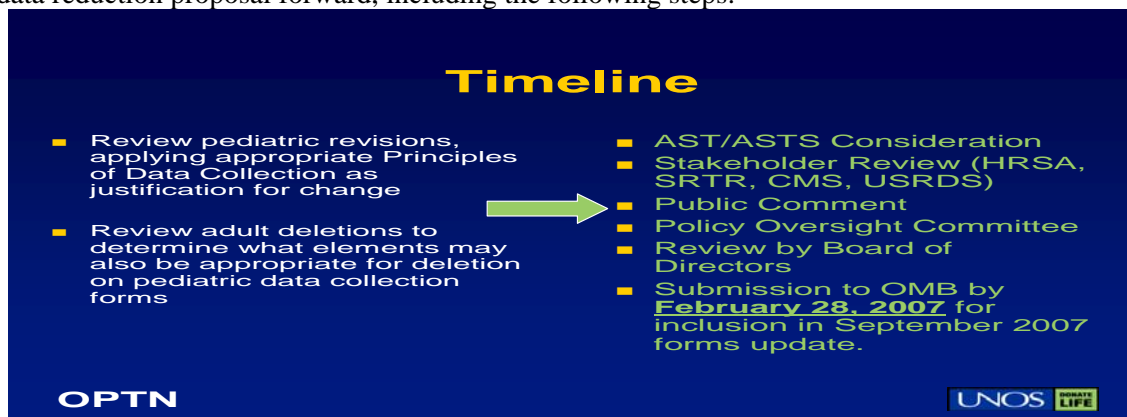
In addition to this request, the Committee plans to respond to the letter of concerns and follow up the recommendation for a conference on these issues by enlisting support to include the topic on the agenda for an upcoming pediatric summit being planned to take place during the first half of 2007. It is expected that the meeting will already include a large number of pediatric intensivists, comprising an essential audience. The Committee believes that this will further and constructively support the JCAHO and OPTN requirements for DCD protocols in all hospitals.

Mr. Charlie Alexander noted that the Joint OPO-MPSC Working Group that developed this proposal is in the final stages of producing model elements document for DCD policies as an outline of things that should be covered. Resources will be solicited from pediatric hospitals that have had greater experience with DCD recovery. He also noted data for from summer 2005 through summer 2006 indicated that there were approximately 200 pediatric DCD organs recovered during this year calendar year. Ms. Jade Perdue reported HRSA's Collaborative efforts have also focused on increasing DCD awareness and utilization for some time. She confirmed that the Collaborative would also be able to assist in circulating information regarding centers that excel at DCD recovery to share the experiences and protocols with other centers still in the developmental stages.

Update Regarding Pediatric Data Collection Revisions.

UNOS Staff provided the Committee with an update of the pediatric data revision process and a timeline for this project to be completed. A conference call was held November 2, 2006, to review the full list of revisions this Subcommittee developed over the last two years (Exhibit C). In light of the community's desire to reduce mandatory data elements, Dr. Estella Alonso encouraged the group to review the list with this new focus in mind. As a result, the original list of recommended additions to pediatric data collection was reduced considerably (Exhibit D). Recognizing that centers are overwhelmed by the current mandatory data requirements, the Subcommittee believes this updated list will be far more palatable to the transplant community. The next step in this process will be a review of the revised adult data collection forms to determine what deletions may also be appropriate and acceptable to the pediatric community.

The time line for this project was outlined. Staff will follow the process used to move the adult data reduction proposal forward, including the following steps:



The Subcommittee will update the full Committee in January, 2007, regarding its progress during its December 1, 2007, conference call to review adult forms and begin finalizing a proposal for consideration by all interested parties. It is expected that the Committee will introduce this proposal to the Policy Oversight Committee during its January 2007, meeting while reporting to the Board of Directors in March.

Dr. Sweet noted that reviewing the adult revisions will prove to be time consuming. He also acknowledged the challenge that will be faced by some adult centers that list pediatric candidates and pediatric centers that continue to list candidates/recipients as they transition to adulthood after their 18th birthdays. Keeping track of two separate sets of forms will be an additional responsibility in these instances.

It was suggested that defining the principles under which a data element is to be considered useful is the key to moving this proposal successfully. It was stressed that data collection costs programs time and money, and this must be appreciated as a final proposal is put into place. Using existing pediatric data registries was discussed as an alternative to mandatory data collection as well as requiring mandatory detailed data collection for a subgroup of patients rather than all registered in UNet SM.

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

Status of Liver and Intestinal Organ Allocation Policy Review.

Evaluation of MELD/PELD Share 15 Policy and Liver Policy Changes on Refinement of Status 1 into 1A and 1B, and Regional Sharing of Pediatric Donors: Waiting List Death Rates and Number of Transplants. The Committee continued its quarterly review of this data, led by Dr. Wida Cherikh (Exhibit E). Wait list mortality rates were reviewed first. It was recognized that both 0-11 and 12-17 age groups listed as Status 1 or 1A/1B after policy changes reflected an increased death rate while adult Status 1 candidates demonstrated a decrease in deaths. Death rates for both children and adolescents listed as MELD/PELD<15 have not increased with the policy changes. While the 0-11 group did not change, the death rate for adolescents listed with a MELD/PELD \geq 15 has increased during the most recent sample period. Adult death rates have not increased during any of the sample periods. Dr. Horslen noted that he was pleased that the younger children that dropped back to MELD/PELD scores when the Status 1 criteria were tightened were not reflecting a higher death rate. This validates the Liver-Intestine and Pediatric Committees' policy changes to tighten these criteria. Dr. Horslen noted that while the adolescent numbers must be watched closely, the increase may appear worse than it is based on the very small numbers within the review cohort.

A review of deceased donor liver transplants noted no substantial increase in the overall number of transplants performed across all age groups within the study cohorts:

For recipients 0-11:

- decrease in percent with Status 1, 1A or 1B
- no change in percent with MELD/PELD<15, although an increase was noted in the last cohort period
- increase in percent with MELD/PELD \geq 15

For recipients 12-17:

- decrease in percent with Status 1, 1A or 1B
- decrease in percent with MELD/PELD<15

- increase in percent with MELD/PELD \geq 15
- For recipients 18 and above:
- no change in percent with Status 1
 - slight decrease in percent with MELD $<$ 15
 - slight increase in percent with MELD \geq 15

Despite small numbers, an increase in the percent of split liver transplant from adult livers to 0-11 recipients was recognized. It was recognized that no split livers were allocated to adolescents during these review periods. This was suggested as a possible opportunity for increasing transplant numbers. Overall, there does not appear to be any difference in the distribution of livers from pediatric donors going to pediatric recipients. Most 0-11 donors went to 0-11 recipients, and most adolescent donors (12-17) were transplanted into adults.

Dr. Sweet noted that there were very few transplants for candidates listed at Status 1B. While recognizing that this is an area to watch, Dr. Horslen noted that the Status 1B criteria had been tightened. He pointed out the higher rate of transplant at MELD/PELD scores of 15 or greater, especially for younger children, stating that many of the children previously listed as Status 1B now fall into this group. The adolescents will be followed here, to determine if they are being disadvantaged with current policy. Dr. Horslen is concerned that the 12-17 year old candidates are not receiving more of the adolescent donor organs, which are frequently placed with adults. At the risk of disadvantaging adult candidates, he recommended consideration of a revision to perhaps direct more adolescent donors to adolescent recipients. As a result, adults would receive more adult donor organs. There is no immediate regional sharing to adolescents due to Share 15. While this does not affect local allocation, once a liver goes to regional allocation, it would be allocated to an adult with a higher MELD score rather than an adolescent based on age. Dr. Horslen recommended pursuing adolescent preference through local and regional allocation, though this will be difficult to address to the Liver-Intestine Committee. The Committee requested further data to review these concerns in more detail that may be used to justify these concerns to the Liver-Intestine Committee. It was recommended this issue be addressed within Dr. McDiarmid's charge to minimize pediatric wait list death. Dr. Sweet noted that the Committee should exercise caution in considering how to address this charge, suggesting that this is a contentious issue that may hinder acceptance in the transplant community overall. He encouraged members to pursue this issue, but cautioned against making it a part of the response to the Committee's charge.

Members also received the results of a request it made for a summary of match runs after the August 24, 2005 policy implementation, showing how often adults are ranked after a pediatric acceptor, the wait list outcome of the adult candidates and wait list death rates. Results showed adults who ranked after pediatric acceptors did not appear to have higher death rates per 1000 patient years in different MELD categories as compared to adults who were never ranked after the pediatric acceptors or to adults on the wait list during the same period.

After review, the Committee determined it will review the summary of match run data in a year. Additionally, it will review the remaining data every six months from this point forward, as it is confident that the numbers remain relatively static.

Pediatric Multi-visceral Transplant by Transplant Center. The Committee reviewed data requested during the July 2006, meeting after reviewing a letter from a center requesting that the 5% threshold for performing transplants on non-resident aliens be reconsidered (Exhibit F). The member noted many of its multi-visceral transplants were performed on young pediatric recipients, many non-resident aliens. The member suggested this procedure is not widely offered

and that the center cannot redirect candidates to other centers with similar experience on performing this procedure. The Committee requested data on the number of multi-visceral transplants, including liver-intestine with or without other organs, performed on pediatric candidates by center. Fifty-six centers had performed multi-organ transplants, with 12 performing 25 or more since October 1987. These data, broken down by organ combination, will be shared with the center offering this concern.

Outcomes of Pediatric Liver and Kidney Transplants with DCD Organs. Dr. Cherikh presented data the Committee requested regarding transplant outcomes for pediatric recipients receiving DCD donor organs (Exhibit G). Kaplan-Meier graft and patient survival information was reported for each organ.

From 1995 to 2004, 31 DCD kidneys were transplanted into pediatric candidates, with nearly 60% (18) being completed between 2002 and 2004. Two-thirds of these organs (22) were transplanted into adolescents. Graft and patient survival rates between brain dead and DCD kidney transplants were not found to be statistically significant; however, the rates were somewhat lower for DCD donor kidneys. At one year, the graft survival rate for DCD donor kidney transplants was 87.1% and 90% for transplants from brain dead donors.

Fourteen pediatric liver transplants were completed using DCD donor organs within the same 1995-2004 time period, with 50% of these transplants completed in 2003-2004. These transplants were nearly evenly divided between younger children and adolescents. Graft and patient survival rates between brain dead and DCD liver transplants were not found statistically different either. At one year, the graft survival rate for DCD donor liver transplants was 92.9% and 78.2% for transplants from brain dead donors.

Status of Kidney Allocation Policy Review.

KARS Update. Dr. Albin Gritsch provided an update of the most recent KARS meeting and modeling that was reviewed in both the Kidney and Pancreas Committee meetings. The SRTR's KPSAM model was completed, and used to test the KARS' proposed allocation policy. Their key components include:

- The pediatric component (giving pediatric candidates preference to donors <35 years of age) will remain the same.
- QENLSB is a major component- a score that calculates the number of years of benefit a recipient will gain as opposed to staying on dialysis. This takes donor age, recipient age, cause of renal failure, matching and PRA into account.

The Kidney Committee agreed that it is not yet ready to use net benefit equations alone for kidney allocation. The next step is modeling, in addition to this, various components for waiting time. Another alternative system was proposed that would involve matching of patients with similar QENLSB scores with donors that were also grouped based on similarities. This too will be modeled for consideration by the Kidney and Pancreas Committees. Dr. Gritsch noted that there was debate within these groups regarding whether the kidney should follow the pancreas or vice versa in allocation where both organs are required for transplant. This issue has not yet been resolved. It was also acknowledged that net benefit scores decrease as age increases, where eventually a point would be reached that there would be no net benefit for receiving a kidney. A subcommittee was formed to address this issue and the ethics of using a pure benefit model that would disadvantage older patients. This issue continues to be considered. A public forum has been scheduled for January to share these issues and the modeling completed thus far prior to

public comment. Details regarding this forum will be shared with this Committee as they are finalized.

It was agreed that pediatric interests are adequately represented at this time, though it is premature to begin modeling for the expected effects of any new allocation system for children specifically. Current modeling does reflect expected breakdown of allocations for children, assuming that the current pediatric preference does not change (Exhibit H). Additional modeling will be added to these simulations, but this provides a current snapshot that benefits pediatric candidates slightly as modeled. It was noted that the QENSLB modeling suggests a projected benefit of one additional year of benefit per transplant. This is recognized as having a potentially huge impact for those awaiting transplant.

Evaluation of Modifications to OPTN/UNOS Policy 3.5.11.5 (Pediatric Priority for Kidneys from Deceased Donors Under Age 35). During its July 2006, meeting the Committee requested data to examine whether or not changes to this policy have resulted in more rapid transplant of pediatric candidates and whether these changes have had any impact of adult transplants and living donor transplants. Preliminary results (Exhibit I) showed that the number and percentage of pediatric kidney transplants from deceased donors less than 35 have increased since this policy change. Consequently, fewer children are waiting for transplant as pediatric candidates appear to be transplanted more quickly than they have in the past. It has been noted that living donor pediatric kidney transplants appear to have decreased since this policy change. The pre- and post- policy change cohorts were recognized as including only five months of wait list additions, and 11 months of transplant data, so the numbers analyzed were relatively small. More analysis will be necessary as additional data becomes available to draw conclusive interpretations. The impact of post-transplant outcomes will also be monitored as more data are available to determine whether the increased number of deceased donor and poorly matched transplants has a negative impact on long term graft survival.

A member noted the lower living donor numbers were expected and discussed in meetings leading up to this policy change. Members predicted a 12-18 month period where living donor numbers might drop as pediatric candidates gained access to these <35 donors within a shorter period of time. Additionally, a lag in reporting living donor transplant may also be responsible for the lower numbers. As a result, the Committee will review this data cohort again in six months to determine if the lag in data submission may have played a role in the lower than expected living donor numbers. Concern was also noted regarding the number of inactive pediatric candidates on the wait list. Some suggested that it may be a matter of wait list management or a way to deal with the increased number of incoming offers under this new policy if candidates are still listed prior to truly needing transplant. This too will be monitored in the future.

Status of Pancreas Allocation Policy Review.

There were no issues for discussion by the Committee regarding pancreata during this time.

Status of Thoracic Organ Allocation Policy Review.

Inferential Data Request: Estimate: Estimate of When 0-11 Candidate LAS Elements Data Set Will Be Robust Enough to Complete Multivariate Analyses. Mr. Jeff Moore provided a brief summary of the requested data (Exhibit J). It will be nearly impossible to do anything nearly exhaustive as the adult LAS model, as the numbers are so much smaller for pediatric candidates when compared to adults. A more limited number of covariates may be considered some time in the near future. As an example, initial results for diagnosis may be available in six months to a

year. However, it will not be possible to build a model for pediatric candidates as extensive as the adult LAS because it would take many decades to accrue the multiple covariates necessary for simultaneous evaluation. Moore suggested that members may be able to review variables for clinical significance and determine what is most interesting to develop a smaller scaled scoring system for 0-11 year old candidates. Dr. Sweet noted this may be a project for the Heart-Lung Working Group in the future.

Discussion of Center-Specific Outcomes Reporting for Lung Transplantation. Dr. Sweet noted concerns within the lung community regarding how the SRTR reports center specific outcomes for lungs as ages 12 and up. A pediatric lung center was reviewed by the Membership and Professional Standards Committee because a subset of its patient population did not meet the expected outcomes. A request has been made to consider this so that other centers are not called for MPSC review perhaps unnecessarily. It was noted that pediatric outcomes are not always similar for adults with the same diagnosis. Dr. Sweet recommended the formation of a Joint Subcommittee with the MPSC to look at this issue in more detail.

New Business

Reports from the Organ Specific Working Groups:

To most effectively address Dr. Sue McDiarmid's charge to the Committee as UNOS President, Dr. Sweet recommended utilizing the Committee's Organ Specific Working Groups to consider ways that pediatric wait list mortality might be reduced within each organ specialty. These groups each met twice by teleconference prior to the full Committee meeting to request and review data as they began to formulate ideas for making practical changes to allocation policy that are expected to result in decreased wait list deaths for children. Progress will be reported to the Board of Directors during its December 2006, meeting.

Status of Heart-Lung Working Group. Dr. Sweet provided the Committee with an overview of the data requested by the Heart-Lung Working Group during its September 26, 2006, conference call and considered by this group during a follow-up teleconference on November 8 (Exhibit **K**) Heart and lung death rates were reviewed by region to look for any significant variability by organ. It was noted that candidates <1 year of age reflected the highest mortality across regions, though substantial variation in these numbers was recognized. In later slides, it was noted that congenital heart disease was responsible for the greatest number of deaths in the 0-5 age group. The highest number of deaths in the 6-10 age group was noted as "other diagnoses." Further review of this category will be completed to determine what conditions were captured within this group. It was also noted that 0-5 year old children on life support, ECMO or VAD were also found to have higher wait list mortality. Some of these children may be too sick to transplant, resulting in death. This will be looked at more closely in future analyses. Not surprisingly, candidates of all age groups listed as Status 1A reflected higher death rates than those listed as Status 1B or 2.

Review of pediatric and adult donors per million populations in both 2004 and 2005 indicated that while the number of adult donors in each region has risen, pediatric donors have declined or remained static in some regions. Great variability was noted in pediatric donors per region. It was suggested that while the OTBC's efforts reflect great results in increasing adult donors, the same cannot be said for pediatric donors. It was recognized that this data does not capture conversion rates, but all agreed that there is work to be done in this area.

In considering data on the distribution of deceased donor hearts from pediatric donors, it was noted that 0-10 donors are transplanted into recipients within this same age group. Alternately, adolescent or 11-17 year old donor hearts were transplanted primarily into adolescent or adult recipients. For lungs, 0-11 donors were used primarily for recipients within the same age group. Donor lungs from adolescents were used for both adolescent and adult recipients. In reviewing the data for both organ types, it appears that only a small fraction of 0-10 year old donor organs go to adults. As a result, the Working Group may consider the impact of allocating organs from these younger donors to recipients ≤ 10 years of age before extending offers to older candidates as a way to transplant more children without disadvantaging the adult population significantly.

The disposition of pediatric donor hearts was also considered. Dr. Wida Cherikh reported that during a one year review period, 44% of 1-5 year-old donor hearts were not recovered, and another 18% were recovered, but not for transplant. The 5-10 age group was also noted with 44% not recovered. In both of these age groups the percentage of hearts transplanted was less than the 44% not recovered, at 33% and 37% respectively. More than 60% of the potentially recoverable organs in the 0-10 age group were not recovered. Reasons included donor age or quality, donor size/weight, and operational concerns related to the transplant center. Similar results were seen for lungs, where the vast majority was not recovered due to donor size/weight. Might these organs have been utilized if an appropriate recipient was located in the allocation process? The Working Group noted that this may be an area where organs could be utilized in emergent critical situations if accepted as an extended or expanded criteria donor. The Group agreed that this is an area that must be looked at more carefully when reviewing turn downs.

The Working Group plans to review the data in more detail and will work to develop a simple plan to identify those 0-10 heart and lung candidates at highest risk for death on the wait list while determining if there are organs not currently utilized that could be transplanted within this population without a negative impact on adult candidates. The SRTR was asked to model regional sharing for 0-11 donor to predict whether there will be a noticeable impact on wait list mortality associated with changes to how these organs are allocated. In addition, work will continue on stratifying 0-11 lung candidates to determine who is most at risk for death on the wait list to develop a pediatric LAS system.

Status of Kidney-Pancreas Working Group. Dr. Albin Gritsch updated the Committee on this group's progress. Data requested during its September 29, 2006, conference call was reviewed on a separate call prior to the start of the full Committee meeting (Exhibit L). It was recognized that wait list mortality is higher in pediatric candidates than expected, and varies by region. The Committee requested that the mortality data it reviewed be further broken down to indicate whether candidates were active or inactive at the time of death. Members agreed that wider regional sharing should be considered for pediatric candidates to decrease wait list mortality and improve patient outcomes. Wait list deaths will be reviewed to determine cause of death, how many offers were turned down, etc. to develop a clearer picture of the data.

In reviewing donor disposition, it was recognized that kidneys from donors < 1 year old were frequently not recovered due to their small size. Outcomes of kidneys transplanted from younger donors will be reviewed more closely to determine if this is a group of organs that could be used more frequently to benefit younger candidates.

The potential impact of multi-organ transplants on kidney allocation in children was also discussed. The Working Group would like to look more specifically at multi-organ allocation policy, specifically kidney-pancreas, and the impact of related payback policies and their effects on children. Paybacks limit a program's ability to utilize local organs in some cases. Members

noted that an increasing number of kidneys are being utilized for liver-kidney transplant. In the case of hepatorenal syndrome, the native kidney function will sometimes improve with the new liver graft. Often, both organs are still transplanted. The Committee requested outcome data for recipients receiving multi-organ transplants where a kidney was utilized to determine if using a kidney in this way is in the best interest of the organ. It was noted that many of these transplants (liver-kidney and heart-kidney) involve adult recipients. If mortality rates are high, are kidneys being utilized wisely? A data request was drafted for review of wait list death rates and outcomes for multi-organ candidates/recipients compared to single organ transplants. Candidate diagnosis and how organs were allocated (locally, regionally or nationally) was also requested to determine if these organs were directed away from pediatric candidates.

Members agreed that current policy is outdated, as kidneys must be considered lifesaving organs. The OTBC initiative to place as many organs per donor was also considered. Members questioned whether multi-organ placements were pursued by OPOs in an effort to place more organs more quickly.

As a result of these discussions, the Pediatric Committee supported (14-0-0) a motion to request the organ specific committee chairs consider an invitation to form a Joint Subcommittee consisting of representation from the Liver-Intestine, Kidney, Pancreas, Thoracic and Pediatric committees to initiate review of all multi-organ allocation policies for the establishment of general principles for multi-organ allocation and reconsider the concept of a kidney as a lifesaving organ that also carries priority similar to that of heart or liver.

It was questioned whether programs were managing their wait lists well, considering the high number of wait list deaths for this group. Were candidates removed from the wait list when they became too sick to transplant or did they die while still actively listed? This too may be influencing the data that was reviewed. A member questioned whether candidates removed as too sick for transplant were too sick because they were not appropriate for transplant or whether they deteriorated due to the long wait for an available and appropriate organ? The data will be reviewed to determine if this higher than expected number of deaths for pediatric candidates can be explained.

Dr. Ruth McDonald offered an abstract that she has been working on that reviewed risk factors for mortality on the wait list and after transplant based on USRDS data. She will be happy to share this with the Kidney Working Group.

Status of Liver-Intestine Working Group. Dr. Simon Horslen provided the Committee with an update of this group's activities from October 17, and November 8, 2006, teleconferences. He reviewed data requested during these calls (Exhibit M). It was noted that mortality rates were higher for both children and adults listed as Status 1 or high MELD/PELD scores. Data indicated that though acute hepatic necrosis and malignant neoplasms reported high death rates for children 0-11, the majority of these deaths were categorized as "other." This area will need to be looked at more closely. Pediatric candidates were recognized as having a higher percentage of re-transplant than adults, while a lower death rate post-transplant was recognized for children versus adults.

The median waiting time for children 0-11 and adolescents 12-17 were also reviewed to determine whether either population had been disadvantaged by changes in allocation policy. In comparing the two sample periods, both adolescents and children appear to wait shorter periods of time for transplant in the most recent cohort.

It was suggested that the key to reducing liver wait list death may be sharing organs more broadly, with wider regional sharing for more critical candidates taking precedent over local transplants of candidates with lower MELD/PELD scores. In considering the disposition of pediatric liver donors, it was noted that approximately 1/4 of all livers from <1 donors and 18% of all 1-5 donor livers are not recovered. This too may be an area where organs can be better utilized to benefit the pediatric candidates. It was noted that many of these organs are not accepted due to size/weight or donor age and quality. As noted previously in the other organ groups, these organs may have been utilized if an appropriate recipient could have been located more quickly than what is accomplished with the current allocation system.

Fall 2006 IT Status Update

Due to time constraints, the Committee will receive an update from the UNOS IT Department during its January 19, 2007, meeting.

**Attendance at the OPTN/UNOS Pediatric Transplantation Committee
Teleconference
November 9, 2005**

Committee Members Attending

Stuart C. Sweet, M.D.	Chair
Simon Horslen, M.D.	Vice Chair
Craig W. Lillehei, M.D.	Region 1
Ian C. Carmody, M.D.	Region 3
H. Albin Gritsch, M.D.	Region 5
Patrick J. Healey, M.D.	Region 6
Sharon M. Bartosh, M.D.	Region 7
Joann C. Dupuis, RN	Region 10
Debra A Dodd, M.D.	Region 11
Estella M. Alonso, M.D.	At Large
Sharon G. DiSano, MS, ARNP	At Large
Sue M. Dunn, RN, BSN, MBA	At Large
Robert Mazor, M.D.	At Large
Pasala S. Ravichandran, M.D.	At Large
Elizabeth Ortiz-Rios, M.D.	Ex Officio
Jade K. Perdue, MPA	Ex Officio

Committee Members Unable to Attend

Thomas M. Fishbein, M.D.	Region 2
John A. Goss, M.D.	Region 4
Ross W. Shepherd, M.D.	Region 8
Morris J. Schoeneman, M.D.	Region 9
Kathie Collins, RN, CCTC	At Large
George B. Mallory, Jr., M.D.	At Large
Amy Palermo	At Large
Jorge D. Reyes, M.D.	Ex Officio

Guests in Attendance

Charles Alexander, RN, MSN	Chair, OPO Committee
Jeffrey D. Punch, M.D.	Membership and Professional Standards Committee
Ruth A. McDonald, M.D.	Board of Directors

UNOS Staff Attending

Sally H. Aungier, Administrator, Department of Member Services
Wida S. Cherikh, Ph.D., Senior Biostatistician/Team Leader, Department of Research
Shandie H. Covington, Policy Analyst, Department of Allocation Policy
Hilary Kleine-Czarda, MSW, Professional Services Coordinator
Leann C., Marcucci, Business Systems Analyst, Department of IT Development
Clifton E. McClenney, Assistant Director, Regional Administration
John D. Rosendale, Biostatistician, Department of Research
Cindy M. Sommers, Esq., Director of Allocation Policy

Arbor Research Collaborative for Health Staff Attending

William E. Harmon, M.D.
John Magee, M.D.
Jeff Moore, M.S.