Interim Report of the
OPTN/UNOS Pediatric Transplantation Committee

November 29, 2007
Chicago, Illinois

The OPTN/UNOS Pediatric Transplantation Committee met on November 29, 2007, and considered the following items:

- Update Regarding Actions from the September 17-18, 2007, Board of Directors Meeting

  The Committee discussed actions from the September 2007 Board of Directors 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.

- 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. 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).

- 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. 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.

- Review of Policies and By-Laws Currently Issued for Public Comment on September 28, 2007

  The Committee reviewed the Membership and Professional Standards Committee's proposal currently out for public comment.

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, 1(10) "*Survival Rates.*"

This proposed change to the Bylaws documents the Membership and Professional Standards Committee's (MPSC) current practice of holding informal discussions with Members during its review of survival rates and activity at transplant programs.

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).

- <u>Review of Policies and Bylaws Currently Issued for Public Comment on November 12, 2007</u>

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

The OPTN/UNOS Living Donor Committee has developed a resource document to help transplant professionals medically evaluate potential living donors. This resource document will also inform and educate potential living donors about their own medical evaluations. This document was originally released for public comment in July 2007 as Guidelines for the Medical Evaluation of Living Kidney Donors. Based on the input from the community, the document is being resubmitted after extensive revision. The Living Donor Committee is now seeking public comment on this revised resource document. Please note that this resource document is not policy and does not carry the same monitoring implications as policy. The Living Donor Committee hopes to improve the care and follow-up of living donors by providing this information for voluntary adoption by transplant centers.

After discussion, the Pediatric Transplantation Committee determined there was no specific pediatric issue requiring further comment.

- <u>Discussion of Living Donor Follow-up Requirements</u> 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. Ruth McDonald, a current member of the Board of Directors, voiced her concerns regarding the follow up requirements during a recent Living Donor Committee meeting. 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 due 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 ex-officio Ruth McDonald were appointed for this Joint Subcommittee.

- <u>Discussion Regarding CMS Volume Requirements for Approval to Transplant Young Adults in Pediatric Centers</u>

Members reviewed a letter drafted by the Chair to CMS detailing his concerns regarding new Conditions of Participation (COPs) that include specific volume requirements for adult transplants that are performed in pediatric transplant centers. 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 out 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 <u>and</u> 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.

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

  - Kidney Allocation Policy Review

    Dr. Sharon M. Bartosh, Kidney Working Group Chair, provided the full Committee with an overview of progress made and data reviewed during its October 15, 2007, conference call. In keeping with the guidelines set forth during the Pediatric Summit, this group has continued its focus on:

    - Determining which children 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 transplants such as adult combined kidney-pancreas or liver-kidney before pediatric offers).

    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 Dr. Wida Cherikh, UNOS Research Staff, 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.

    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 to get a clearer understanding about factors that lead to death on the pediatric kidney wait list. 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.

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 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 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. The Committee requested the number of offers from and accepted from donors ≥ 35 years of age.

Evaluation of Share 35 Policy – Preference for Kidneys from Pediatric Donors Age < 35 Years 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. The Committee was interested in studying if graft survival is going to be worse with the higher percentage of deceased donors and less well matched kidneys since Share 35 was implemented. Results indicated that there are 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 to 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.

Sensitized Pediatric Candidates and Kidney Allocation Concerns were raised that upon implementation of Share 35 Policy, 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. 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, 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.

Kidney Committee Progress Update The Committee received an update on recent activity in the Kidney Transplantation Committee as it continues to develop a concept proposal for a new kidney allocation system (KAS). A public comment document is expected 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 KAS 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 Working Group 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.

- Thoracic Organ Allocation Policy Review

Dr. Stuart Sweet, Heart-Lung Working Group Chair, provided the full Committee with an overview of progress made and data reviewed during its September 25, 2007, conference call. Separate heart and lung proposals are under development based on the Working Group's progress over the last 18 months. He presented a progress report to the Thoracic Committee in October, and this group was 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 suggested modifications developed by Working Group members. The heart proposal will specifically addresses 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 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 to first to younger children. Because historically, only 0.5% of adults and 12% of adolescents have received hearts from donors less than 12 years old, the Working Group believes that prioritizing 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 affect 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. The original proposal broadly shared only 0-10 year old organs. The cost is the potential for more travel to the center, but 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 addresses 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. 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 these 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: patients with respiratory failure or refractory pulmonary hypertension

- Further defining candidates with respiratory failure as:
  - PCO_2 > 60,
  - Full time ventilation, or
  - Full time bi-PAP

- Defining refractory pulmonary hypertension based on super-systemic pressures in the face of multi-drug therapy

Status 2: all remaining candidates

(2) 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.

The second component 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, but agreed that this was an area of discussion that could be considered in conjunction with the full Thoracic Committee.

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.

Estimate of Time Needed to Accrue Enough Data to Evaluate July 2006 Heart Policy Change for Pediatric Patients The Committee reviewed data estimating 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. 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 is not practical 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). 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 this policy. 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.

Lung Allocation Score (LAS) System Update: The First Two Years The Committee was reminded to review these slides independently after the meeting. 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.

Update from Joint Pediatric-Membership and Professional Standards Committee Data Subcommittee (MPSC-DS) Considering Changes to Lung Outcome Review Process Center specific reports and outcome tracking measures 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. What is the survival of adolescents overall for patients in predominantly adult programs versus predominantly pediatric programs? This group will reconvene in January to review this additional data at a soon to be scheduled meeting, anticipated for January 2008.

Expanding the Adolescent Candidate Window within the LAS Concerns were raised during the Thoracic Committee's October 3, 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, as this should be expected to direct more organs to children in the long run, and will look forward to reviewing the modeling data.

- Liver and Intestinal Organ Allocation Policy Review

Dr. Simon Horslen, Liver-Intestine Working Group Chair, provided the full Committee with an overview of progress made and data reviewed during its October 19, 2007, conference call. 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.

This 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 this 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 have been tentatively drawn up as options for consideration. The Working Group will meet with representatives from the Liver and Intestinal Organ Transplantation Committees 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. 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.

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.

Outcomes of Pediatric Liver and Kidney Transplants from DCD Donors Committee members reviewed Kaplan-Meier graft and patient survival of pediatric recipients of DCD donors, originally requested by the Liver-Intestine Working Group.

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 looked at more closely. A member suggested the importance of sharing this information with the pediatric intensivist 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 The Committee discussed a 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 the RRBs. The Committee reviewed data, but did not see any blatant areas of concerns. Overall, children seemed to fare better than adults in the review process overall. 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 take a closer look at these anecdotal concerns.

A 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-Intestine 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 is now obsolete and inaccurate. 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.

- 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. 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.

- 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 raises 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. 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.

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