

**Interim Report of the  
OPTN/UNOS Pediatric Transplantation Committee**

**July 12, 2007  
Chicago, Illinois**

*The OPTN/UNOS Pediatric Transplantation Committee met on July 12, 2007, and considered the following items:*

- Introduction of New Committee Members and Brief Orientation

Drs. Sweet and Horslen, Committee Chair and Vice-Chair, welcomed new members to the Committee. Ms. Shandie Covington, Committee Liaison, 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.

- Update Regarding Actions from the June 26, 2007, Board of Directors Meeting

The Committee discussed actions from the June 2007 Board of Directors meeting. 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.

- Update on HHS Program Goals

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. 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.

- Review of Policies and By-Laws Currently Issued for Public Comment on June 15, 2007

The Committee reviewed the four proposals currently out for public comment, and provided the following feedback:

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)
- Review of Policies and Bylaws Currently Issued for Public Comment on July 13, 2007

The Committee reviewed the four proposals currently out for public comment, and provided the following feedback:

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)

- Kidney Allocation Policy Review

The Kidney Working Group Chair, Dr. Sharon Bartosh, provided members with a brief update regarding the latest round of data that were reviewed, 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 this fall.

Ms. Covington and Dr. Mark Fox, crossover representative for these two Committees, provided members with a brief update regarding the Kidney Committee's progress on its ongoing allocation policy development.

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. 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. 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 do 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 offers from and accepted donors  $\geq 35$  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 worse 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.

- Thoracic Organ Allocation Policy Review

The Thoracic 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. The Committee voted unanimously (17-0-0) to share the Working Group recommendations with the Thoracic Committee this fall.

The Committee heard a summary report from the May 11, 2007 Joint Pediatric- Membership and Professional Standards Subcommittee (MPSC) teleconference. This group considered concerns related to the outcomes review process for pediatric lung programs. The SRTR is currently studying whether the  $\leq 11$  year-old and  $\geq 12$  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 SRTR presented data assessing the impact of broader sharing of 0-11 donor hearts and lungs for pediatric candidates. 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 organ 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.

The Committee did not review the standard LAS update at this meeting, 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.

○ Liver and Intestinal Organ Allocation Policy Review

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. The Committee voted unanimously (17-0-0) to share the Working Group recommendations with the Liver Committee this fall. 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.

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 has been 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 this meeting, Dr. Cherikh presented wait list death rates data 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.

The Committee reviewed updated SRTR data outlining the potential benefits of recalculating PELD coefficients. 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.

○ Effects of Hormonal Resuscitation on Organ Utilization in Pediatric Donors

Dr. Cherikh provided the committee with a brief overview of recent research regarding the effects of using hormonal resuscitation in pediatric donors on organ utilizations. This information was also shared during the Pediatric Summit in March 2007.

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