

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

**March 27, 2007  
San Antonio, Texas**

*The OPTN/UNOS Pediatric Transplantation Committee met on March 27, 2007, and considered the following items:*

- Update Regarding Actions from the March 23, 2007, Board of Directors Meeting

The Committee discussed actions from the March 2007 Board of Directors meeting. Minutes were not available at the time of this meeting. Of specific interest to this committee were the Board approved modifications to Policy 3.7.6.1 (Lung Allocation - Candidates Age 12 and Older) to include PCO<sub>2</sub> in the Lung Allocation Score using the lower 90% confidence limits for the hazard ratios associated with the most recent values of PCO<sub>2</sub> and an increase in PCO<sub>2</sub> greater than or equal to 15% in the previous six-month period. Additionally, it was noted that the Board approved modifications to the Bylaws, Appendix B, Attachment I, Section VI "Transplant Surgeon & Physician," and Section XII(C) "Transplant Programs," to clarify what "on site" means with relation to the availability of transplant surgeons and physicians to provide service to their patients in need of organ transplantation. The objective is to make existing criteria regarding physician and surgeon availability more specific. The Board also approved additional amendments to this proposal to require transplant programs to provide a copy of the Program Coverage Plan to patients and to require that programs have a surgeon and physician available 24/7/365.

- Update on HHS Program Goals

The Committee was provided an update on the HHS Program Goals. 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 March 2, 2007

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

1. *Proposed Modifications to Data Elements for Pediatric Candidates and Recipients on UNet<sup>SM</sup> Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), and Transplant Recipient Follow-up (TRF) Forms (Pediatric Transplantation Committee)* The Committee sponsored this proposal and will consider all individual and regional feedback at the end of the public comment period, April 30, 2007 in preparation for presenting this proposal to the Policy Oversight Committee and the Board of Directors.

2. *Proposed Modifications to OPTN/UNOS Policy 7.1.5 "Reporting of Definitions" and OPTN/UNOS Policy 7.3.2 "Submission of Organ-Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Form" (Living Donor Committee)* After discussion, the Committee determined that there was no specific pediatric issue requiring further comment. Members did underscore the lack of long-term follow-up for these living donors. The number of living donors that are lost to follow-up was concerning to the Committee. It was recognized that because there is no current requirement to retrieve this information, marking these individuals as "lost to follow-up" still meets the criteria for a completed form. Members believe this attempt to collect meaningful data is a first step in addressing this problem.
3. *Proposed Modifications to OPTN/UNOS Policy 7.3.3 "Submission of Living Donor Death and Organ Failure Data" (Living Donor Committee)* After discussion, the Committee determined there was no specific pediatric issue requiring further comment.
4. *Proposed Modifications to the UNet<sup>SM</sup> Living Donor Registration (LDR) and Living Donor Follow-up (LDF) Forms (Living Donor Committee)* After discussion, the Committee voiced concerns regarding freestanding pediatric programs that must track adult living donors. The Committee voted in support of this proposal, but requests the Living Donor Committee clarify the responsibility of transplant centers that utilize a living donor organ but do not see or treat the living donor. Current policy places the responsibility of follow-up on the recipient transplant center. This is not practical in the case of freestanding pediatric centers, and may not be practical in other instances as well. Members voiced concerns that pediatric programs should share responsibility for providing long term follow-up information about adult living donors with the programs/physicians that procured the donor organs. The Committee recommends that information regarding the living donor's center be collected and the Living Donor Committee consider how to use this information to follow these individuals more effectively. (Committee vote: 12-0-0)
5. *Proposed Modifications to Data Elements on UNet<sup>SM</sup> Deceased Donor Registration (DDR) From (Organ Availability Committee)* Committee members questioned whether the Organ Availability Committee's requested information might be more practically gathered as part of a research project, where these data elements could be gathered at centers that are interested in participating. It was acknowledged that this level of detail would be beneficial in placing organs by allowing better assessment for the DCD organ at time of offer. A member suggested that many OPOs may already be doing this, though not to the specifications outlined within the proposal. Additionally, an intensivist on the Committee questioned whether this data collection might interfere with withdrawal of care protocols in place at some pediatric centers. The necessity of minute-by minute urine output was also questioned by members. After discussion, the Committee voted to support the proposal, but requests the Organ Availability Committee consider: (1) selecting an end date for this level of data collection, then reviewing what was collected and its benefits and/or unintended effects on the DCD recovery process, (2) the necessity of minute-by-minute urine output collection, and (3) the effects of these requirements on withdrawal of care protocols already in place in many pediatric centers. (Committee vote: 12-0-0)

6. *Proposed Imminent Neurological and Eligible Death Definition Data Elements (OPO Committee)* After consideration, members questioned whether there is a mechanism within HRSA to evaluate pediatric ICUs and whether the proposed definitions are broad enough. Would a pilot study, including community hospitals without transplant programs, be more appropriate in capturing this information? Members questioned whether pediatric numbers may be underestimated using these definitions. It was acknowledged that current practice includes real time or retrospective medical records reviews. This is not information that is currently being reported in UNet<sup>SM</sup>. The added burden of transitioning from aggregate to individual data was acknowledged for the OPO community, but is required by the new OPTN contract. After discussion, the Committee voted to support the proposal, but asks the OPO Committee to consider whether this proposal may adequately address the pediatric population. A recommendation was made to consider a review this data after a period of time to determine if the ranges set within these definitions have been appropriately set for pediatric patients. (Committee vote: 12-0-0)
7. *Proposed Modification to OPTN and UNOS Bylaws, Appendix A2-1, Section 2.06A, (b) "Probation," (4) "Member Not in Good Standing" (5) "Suspension of Member Privileges," (6)"Termination of Membership or Designated Transplant Program Status," (7) "Action Specified in OPTN Final Rule,": (Patient Affairs Committee)* After discussion, the Committee determined there was no specific pediatric issue requiring further comment.

- Discussion Regarding Pediatric Summit on Organ Donation and Transplantation

The Committee briefly discussed the format of the day and a half meeting to be held following this Committee meeting, bringing pediatric intensivists, pediatric transplant physicians and surgeons, OPO staff and other clinicians working in pediatric organ donation and transplantation together to address the problem of death on the pediatric wait list. The Organ Specific Working Groups were to share data requested and reviewed over the past five months as they worked to address Dr. McDiarmid's charge to this Committee- reduce death on the pediatric wait list. The current focus appears to be redirecting organs from 0-10 donors to 0-10 candidates, which should have little to no affect on the adult population. Ideas will be shared with Summit participants, and discussion is expected to perhaps further some of the ideas that have already been generated within the individual Working Groups.

The Committee's January 2007 recommendation to require a match run be generated for every consented organ was discussed during the February 2007 OPO Committee meeting. After consideration, because there are legitimate reasons why match runs for consented organs may not be run, it was suggested that this idea be reframed and introduced at the April 2007 Collaborative Learning session as a PDSA to encourage real time partnership between pediatric transplant professionals and OPOs working to place small or marginal pediatric organs. It is hoped that this real-time dialogue with pediatric transplant professionals will assist OPO personnel in determining when to continue pursuing placement of pediatric organs in instances where placement may be prematurely halted or organs may not be considered for recovery at all. It is anticipated that this effort may help in the Committee's efforts to meet its charge of decreasing pediatric death on the wait list by making more organs available to the most critical candidates.

- Heart-Lung Working Group Presentation

The Heart-Lung Working Group presented the latest iteration of data it reviewed during its March 5 conference call. This information will be incorporated into the Group's presentation during the physician-surgeon track of the Pediatric Summit, to be held on the following day.

- Kidney Working Group Presentation

The Kidney Working Group presented the latest iteration of data it reviewed during its March 6 conference call. This information will be incorporated into the Group's presentation during the physician-surgeon track of the Pediatric Summit, to be held on the following day.

- Liver-Intestine Working Group Presentation

The Liver-Intestine Working Group presented the latest iteration of data it reviewed during its March 2 conference call. This information will be incorporated into the Group's presentation during the physician-surgeon track of the Pediatric Summit, to be held on the following day.

- Status of Kidney Allocation Policy Review

The Committee received an update on the February 8, 2007, Public Forum held to share progress made on kidney allocation policy development. It was noted that there have been no recommended changes to pediatric allocation at this time, with pediatric candidates still receiving preference for donors <35 years of age.

Concerns were raised regarding sensitized pediatric candidates priority within the current allocation system. Under current policy, pediatric priority falls in the allocation algorithm after zero antigen mismatched candidates, sensitized candidates (PRA  $\geq 80\%$ ) who otherwise would rank highest in allocation priority, combined kidney non-renal organ candidates, and prior living organ donors. This preserves priorities for these candidate groups, which have been established based upon medical criteria, including utility of outcomes and biological barriers to transplantation.

Concern regarding how a highly sensitized pediatric candidate may be disadvantaged in cases where there is a highly sensitized adult candidate was acknowledged. UNOS staff will review the number of times a highly sensitized pediatric candidate has been usurped by a highly sensitized adult candidate. The Committee is currently aware of only one incident where a pediatric candidate may have been in this scenario. The Committee will receive follow-up on the number of incidents, and a Joint Subcommittee will be formed with the Kidney Transplantation Committee if necessary to address this issue.

- Status of Thoracic Organ Allocation Policy Review

The Committee was reminded of an upcoming teleconference for the newly formed Joint Pediatric-Membership and Professional Standards Subcommittee to review center-

specific outcomes reporting for pediatric lung programs. Appointments have been made from both Committees, and a call will be scheduled for May, 2007.

- Status of Liver and Intestinal Allocation Policy Review

The SRTR presented the results of an updated analysis on results of recalculating the PELD coefficients. This presentation provided an update to information considered during the January 19, 2007, meeting. It was noted that none of the variables that are NOT in the current PELD equation were significant predictors of mortality on the waiting list, and that there were no significant interactions between variables. The SRTR will use the Liver Simulated Allocation Model (LSAM) to estimate waiting list mortality and net change in the number of transplants resulting from an allocation system using updated coefficients (PELD 2) for pediatric patients compared with an allocation system using current coefficients (PELD 0) for pediatric patients. Results will be shared upon completion of this modeling.

The Committee will continue to monitor concerns regarding adolescent liver candidates with MELD>25 and work with the Liver and Intestinal Organ Allocation Committee to determine whether allocation priority should be adjusted to better serve this population.

- Winter/Spring IT Update

The Committee received an update from UNOS IT Staff regarding the continued roll out of DonorNet 2007 in DSAs across the country. An update on the Enterprise System Redesign Project, a ground up redevelopment of the Systems utilized at UNOS to support the OPTN, was also provided. The current system does not allow for increased efficiency and productivity, and reporting capabilities are insufficient for the OPTN's current needs. Work is being done to develop a format compatible with electronic health records (EHRs) that will be used in hospitals across the country as well as increase interface with other databases that will allow for sampling for research purposes. Staff noted that the final iteration of this project may be the creation of a separate pediatric allocation system. It was noted that a number of staff will be reassigned to this project, pulling resources from Committee support personnel to complete this process.

- Update on Tiered Acceptance/DSA Task Force

The Committee heard an overview of the tiered acceptance project, which is being designed to improve efficiency in the organ placement process. The Committee reviewed information that was approved in general concept by the Liver and Intestinal Organ Transplantation Committee during its March 6, 2007, meeting.

- Recognition of Outgoing Committee Members, Terms Ending June 30, 2007

Dr. Sweet acknowledged those Committee members whose terms were expiring in June 2007 for their time and participation on the Pediatric Transplantation Committee. Each outgoing member will receive a certificate recognizing his or her participation.

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