

EXECUTIVE SUMMARY
OF THE MINUTES
OPTN/UNOS
BOARD OF DIRECTORS MEETING
November 18-19, 2004
Reston, Virginia

Dr. Metzger called the meeting to order at 8:30 a.m. on November 18, 2003. A quorum was present, and 34 of the Board members were in attendance during the meeting.

The Board appointed Dr. Kim M. Olthoff to fill the vacancy created by the relocation of Dr. Andrew S. Klein as the Region 2 Councillor on the Board of Directors. The Board also appointed Dr. Donald J. Hillenbrand to fill the vacancy created by the resignation of Laurie S. Garretson, as the Region 5 Councillor on the Board of Directors.

Malcolm E. Ritsch, Jr., Esq., UNOS General Counsel, gave a brief presentation to the Board regarding existing guidelines for identifying and managing potential conflicts of interest.

The Board approved several resolutions contained in the Consent Agenda in a single vote. The subject of the various individual resolutions follows here:

1. The Board approved modifications to UNOS Bylaws Appendix B, Attachment II-A (Standards for Histocompatibility Testing) that will remove clinical practice standards; make them less detailed; rearrange the standards into more meaningful sections; and add standards on pancreatic islet cell transplantation and solid phase multi channel arrays.
2. The Board approved modifications to Policy 2.7.1 (Multiple Abdominal Organ Procurement) to clarify why consented pancreata are not recovered by increasing the knowledge base to help determine why pancreata are not being recovered in the presence of anatomical abnormalities.
3. The Board approved modifications to Policy 4.0 (Acquired Immune Deficiency Syndrome (AIDS) and Human Pituitary Derived Growth Hormone (HPDGH) and Human T-Lymphotropic Virus Type 1 (HTLV-1)) that will allow individuals who received HPDGH from human tissue and individuals who test positive for HTLV to be evaluated as potential organ donors. The modifications will also establish a formal system for prompt reporting of cases where transmissible diseases are detected in a donor after organs are procured, or before or after transplant.
4. The Board approved modifications to Policies 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Material), 2.5.7 (Proper Packaging of Paperwork to Accompany Organ), and 2.5.7.1 (Written Documentation Accompanying Each Organ) that will require that the external surface of the outer container of transported organs or specimens utilize a standardized label; that all previously used

external labels be removed from the outer container prior to transport; and specify further documentation requirements and protocols.

5. The Board reaffirmed the principle of communication between OPOs and Transplant Centers, but that information provided to donor families and recipients remain non-identifying to protect the confidentiality of the donor, the recipient, and their families.
6. The Board approved Lung Review Board Operational Guidelines and associated modifications to Policy 3.7.6.3 (Candidate Variables in UNetsm) and 3.7.6.4 (Lung Candidates with Exceptional Cases) that will provide prospective review of estimated values for lung allocation scores as well as review of exceptional cases.
7. The Board reaffirmed LifeSource's request for a local alternative allocation system for pancreatic islets to define the criteria for the pancreata that would be used for islet transplantation.
8. The Board approved modifications to the Region 7 Sharing Agreement that will include donors less than one year of age on the list of donor organs that will not be offered for payback.
9. The Board approved a thoracic organ variance requested by Organ Donor Center of Hawaii (HIOP), whereby thoracic organs from Hawaii donors will be offered first locally, and then to Zone X which will extend to all transplant centers within 2,500 miles of Honolulu, and then to Zone Y which will extend to all centers that are beyond 2,500 miles of Honolulu.
10. The Board approved a thoracic organ variance requested by LifeCenter Northwest (WALC), whereby it will offer thoracic organs, where the donor is from Alaska, through the end of Zone C prior to making offers to closer transplant centers in Canada.
11. The Board approved modifications to Policies 7.2 (General Submission of OPTN Forms) and 7.3 (Submission of Organ-Specific Transplant Recipient Registration Forms) to reflect the accurate expected due dates for forms.
12. The Board approved resolution to endorse Fistula First, a National Vascular Access Improvement Initiative.
13. The Board approved modifications to Policy 3.5.11.1 (Time of Waiting) to adopt the CMS definition of chronic maintenance dialysis.
14. The Board approved new Policy 3.2.8 (Previous Kidney Donor Antigens Considered "Self" Antigens in Pancreas Match Runs) to clarify the use of HLA antigens in pancreas match runs.
15. The Board directed that ascites and encephalopathy data for adolescent candidates shall be collected on the liver transplant waiting list, and that a method for better gradation of these conditions should be developed that would apply to adults and adolescents.
16. The Board approved membership changes including one new transplant center; two new programs in existing member centers; two new independent histocompatibility laboratories; and nine pancreas islet transplant programs.
17. The Board approved requests for new and to renew Medical/Scientific, Public Organizations, and Individual memberships for members that desired to continue their membership for another two-year term.
18. Recommendation to grant full approval to two transplant programs that now meet the membership requirements.
19. The Board approved modifications to Bylaws Appendix A, Section 1.04A (Processing the Application) to clarify the need for applications to be complete prior to submission to

the MPSC; the role of UNOS staff in reviewing applications for completeness; and the specific elements that must be provided with complete applications.

20. The Board approved modifications to OPTN/UNOS Bylaws Attachment I to Appendix B, Section V. (Histocompatibility Laboratory Affiliation) to clarify that a non-member hospital based histocompatibility laboratory may satisfy a transplant center's histocompatibility laboratory affiliation membership requirement.
21. The Board approved modifications to Policy 3.7.2 (Geographic Sequence of Thoracic Organ Allocation) that will add greater clarity to the policy language describing Zone C.
22. The Board approved modifications to Policy 3.7.7 (Allocation of Thoracic Organs to Heart Lung Candidates) to clarify which ABO measurement should take precedence in a heart-lung match.

The Board endorsed the concept of the establishment and administration of a National Live Paired Kidney Donation (LPKD) Program through the OPTN/UNOS with the understanding that the details of the program will be developed over time.

The Board approved modifications to Policies 3.5.5 (Payback Requirements) and 3.5.11.5 (Pediatric Kidney Transplant Candidates) that will provide priority for allocation of standard criteria deceased donor kidneys from donors less than 35 years to pediatric candidates listed prior to age 18 locally, regionally, then nationally. These modifications shall be applied to OPOs operating with approved alternative allocation systems provided that OPOs have an ample opportunity to submit an application to continue their current kidney alternative allocation protocol.

The Board approved modifications to Policy 3.6 (Pediatric Donor Liver Allocation Algorithm) that alter the sequence for allocation of pediatric donor livers.

The Board approved modifications to Policies 3.6.4.1 (Adult Patient Status) and 3.6.4.2 (Pediatric Patient Status), which provide more stringent definitions of Status 1 for adult and pediatric liver transplant candidates. All portions of Policy 3.6 pertaining to Status 1 have been modified to reflect these changes. Performance goals will be established for this policy modification and will be used to study whether further modifications are warranted to address portal vein thrombosis.

The Board granted final approval to a set of Standard Guidelines for MELD/PELD Exceptions that are intended to promote consistent review of these exceptional cases throughout the country, as revised to substitute metabolic diseases “treatable with liver transplantation” for metabolic diseases “producing coma” and also to reflect the accurate designation of “primary hyperoxaluria” within the Guidelines.

The Board approved revisions to the Region 5 Status 1 Liver Sharing Agreement that will use revised definitions for Status 1; eliminate paybacks; implement retrospective review of all Status 1 listings; and will be evaluated at 6 months and 1 year after implementation.

The Board established an ad hoc committee to review the organ payback system.

The Board approved modifications to Policy 3.7.3 (Adult Patient Status) that will allow each region to decide for itself whether to institute prospective or retrospective review of heart Status 1A exception listings.

In a single vote, the Board directed that the Karnofsky Index replace the current method of collecting functional status on the OPTN data collection forms with the addition of an “unknown” option to the scale and directed that the Karnofsky Index be implemented on March 1, 2005, for transplant candidates and recipients 17 years and older. The Board also directed that the Lansky Score replace the current method of collecting functional status on the current data collection forms for children 1 to 16 year of age, with an addition of an “unknown” option to the scale. For pediatric patients less than one year old, the Lansky Score is not applicable, so an answer of “N/A” will be selected for these patients.

The Board approved modifications to Policies 3.5.9 (Minimum Information/Tissue for Kidney Offer), 3.8.5.1 (Minimum Information for Pancreas Offers), and 3.2.1.5 (Renal and Renal-Pancreas Combination Patient Listing) that will specify that full HLA typing results must be provided by the Host OPO for deceased kidney and pancreas donors.

The Board directed that the College of American Pathologists (CAP) be granted “Deemed Status” by UNOS such that any histocompatibility laboratory that provides service for an OPTN/UNOS member transplant center and is accredited by the CAP in histocompatibility testing for solid organ transplantation would be accepted by UNOS as being in compliance with UNOS histocompatibility standards, effective pending execution of an agreement between CAP and UNOS.

The Board approved new Policy 7.9 (Data Submission – Non-compliance) that will require UNOS staff to conduct onsite audits at the member’s expense of members that are non-compliant with data submission requirements.

The Board approved significant modifications to Policies 3.1 *et seq.* (Definitions) and 3.4.6 *et seq.* (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems), as well as new Policies 3.4.7 *et seq.* (Application, Review, Dissolution and Modification Processes for Variances) regarding application for and review of organ allocation or distribution systems that differ from the applicable standard national organ allocation or distribution system. Additional modifications were approved specifying that applications for AAD Systems may specify as its purpose enhanced organ quality and anticipated difficulties in the proposed AAD System to aid in the evaluation of the System.

The Board approved a proposal to promote participation in the public comment process including the simplification of public comment summary information so that interested parties from all constituencies are provided opportunities to participate in the process.

The Board approved a proposal to initiate a national survey to determine baseline information of the views of the general public regarding transplantation.

The Board directed that simplified language used in the public comment process and the national survey to determine the views of the general public regarding transplantation shall be undertaken in a culturally competent method and subject to the availability of personnel and financial resources.

The Board approved modifications to match run programming that will allow the match system to screen thoracic organ candidates from the match run based on their distance from the donor.

The Board approved a “Statement Regarding Solicitation of Deceased Donation” to provide guidance for members involved in instances of public solicitation for directed donation of a deceased donor organ.

The Board approved a resolution opposing the unsolicited contact by individuals with potential deceased donor families seeking to obtain a donated organ through directed donation.

The Board initially tabled a proposed new policy regarding vascular allografts. Later in the meeting, the Board approved for public comment only, proposed new Policy 5.8 (Vessel Recovery, Storage, and Transplant), which provides guidance for the recovery, use, and storage of deceased donor vascular allografts.

The Board approved Carolina Donor Services’ request for a local pancreas and kidney-pancreas alternative allocation system to specify that only well-matched isolated pancreas candidates will receive priority over candidates waiting for a combined kidney-pancreas transplant.

The Board declined to delay the implementation of the Missouri State ALU.

The Board charged the Liver and Intestinal Organ Transplantation Committee to model the anticipated mortality effects on pediatric and adult candidates, of the pediatric donor liver allocation policy passed earlier in the meeting and to determine whether or not there should be a minimum PELD score for regional sharing of pediatric donor livers.

The Board approved the Evaluation Plan that describes in detail how UNOS, as the OPTN contractor, will implement requirements of the OPTN Final Rule related to compliance and monitoring.

The Board approved the Board Composition Plan and the slate of nominees for election of members of the Board of Directors, as amended from the floor to include Paul B. Oldam, BSS, and Flora Solarz, MPS.

The Board approved modifications to the Regional Review Board Operational Guidelines.

The Board directed that lung candidate waitlist forms be programmed to accept a list of additional candidate clinical variables that may be updated voluntarily by listing centers.

The Board approved goals for thoracic allocation policy development.

The Board directed that membership on the Regional Review Boards should not include physicians and surgeons who are not active in the field of organ transplantation corresponding to the organ-specific Regional Review Board.

The Board approved modifications to the OPTN Charter Article III (Board of Directors) and OPTN/UNOS Bylaws Section 2.3 (Number) to increase the maximum number of directors on the Board of Directors to 42 and designate the additional director to represent pediatric-specific interests.