

EXECUTIVE SUMMARY
OF THE MINUTES
OPTN/UNOS
BOARD OF DIRECTORS MEETING
November 17-18, 2005
Reston, Virginia

Dr. Delmonico called the meeting to order at 8:30 a.m. on November 17, 2005. A quorum was present, and 37 of the Board members were in attendance during the meeting.

The Board appointed Dr. Richard J. Howard to fill the vacancy created by the resignation of Abraham Shaked, M.D., Ph.D. as the Medical/Scientific Representative (ASTS) on the Board of Directors.

After extensive discussion of the financial condition of the OPTN, the Board approved the following four resolutions in a single vote:

The Board approved the 2006 OPTN operating budget and registration fee based on the approved budget for the recently awarded OPTN Contract, effective September 30, 2005.

The Board directed that committee recommendations to the Board shall include a cost analysis or fiscal impact statement for the OPTN and its members.

The Board directed that the Executive Director work with the Executive Committee to examine structures and processes that have a financial impact on OPTN Operations, including the number of committees, frequency of meetings, and how committees meet, to develop ways to minimize OPTN costs.

The Board resolved to encourage the Department of Health and Human Services to work with Congress to increase the authorized amount of federal funding for the OPTN and appropriate additional funds to support OPTN operations in recognition that the cost of OPTN operations has increased significantly since the passage of National Organ Transplant Act (NOTA) in 1984, while the amount of federal funding authorized by NOTA has not changed since 1984.

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 the Bylaws Appendix B – Attachment II-A (Standards for Histocompatibility Testing) to update the standards as changes occur in current procedures and practices in laboratory practice.
2. The Board approved the proposal to delete Policy 3.5.10 (Preservation Mode of Shared Kidneys) as it appears outdated and departs from current practices.
3. The Board approved a proposal to screen pancreatic islet candidates from the match run based upon maximum acceptable distance criteria.
4. The Board approved revisions to the Renal Minimum Acceptance Criteria questionnaire to increase its effectiveness as a screening tool for organ placement.
5. The Board approved the Regional Review Board Guidelines for use by the Liver Regional Review Boards.

6. The Board granted final approval, post-public comment, to modifications to Policy 3.6.4.1 (Adult Patient Status) that would remove the current minimum listing requirement for adult transplant candidates.
7. The Board approved modifications to Policy 2.6 (Initiating Organ Procurement and Placement), and 3.1 (Organ Distribution) that would reflect current practice and conform to the Final Rule definitions.
8. The Board granted final approval to modifications to Policy 3.7.6.3 (Candidate Variables in UNetsm) and Policy 3.7.9 (Time Waiting for Thoracic Organ Candidates), that would allow missing heart catheterization values to default to normal pulmonary pressure values.
9. The Board approved revisions to the Bylaws, Article VII (Permanent Standing Committees) to accommodate the creation of the Policy Oversight Committee, which is a new committee required under the new OPTN Contract.
10. The Board approved a proposal to require the collection of encephalopathy and ascites data only at initial listing and upon removal from the liver waiting list.
11. The Board approved modifications to Policies 3.6.4.1 (Adult Candidate Status) and 3.6.4.2 (Pediatric Candidate Status) that will create consistency between the policy language and the UNetsm programming.
12. The Board approved modifications to Policies 3.6.4.1 (Adult Candidate Status), 3.6.4.2 (Pediatric Candidate Status), 3.6.4.3 (Pediatric Liver Transplant Candidates with Metabolic Diseases), 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)), and 3.6.4.5 (Liver Candidates with Exceptional Cases) that will create consistency in the policy language across the liver and thoracic allocation policies.
13. The Board approved membership changes including one new transplant center; four new programs in existing member centers; two pancreas islet transplant programs; thirteen live donor liver programs; and one new hospital-based histocompatibility laboratory.
14. The Board approved applications for new and to renew the membership of non-institutional members that desired to continue their membership for another two-year term.
15. The Board approved requests to grant full approval to three programs that now fully meet membership requirements.
16. The Board approved modifications to the Bylaws, Appendix A, Section 1.01A (Nature of Membership/Designated Transplant Program Status) that would clarify the need to create an alternate pathway of approval for facilities that intend to transplant pancreata only as part of a multi-visceral block transplant and to grant approval to one new program under this requirement.
17. The Board approved the official minutes of the June 23-24, 2005, meeting of the Board of Directors in St. Louis, Missouri.
18. The Board approved modifications to Policy 3.7.9.2 (Waiting Time Accrual for Lung Candidates Age 12 and Older following Implementation of Lung Allocation Scores Described in Policy 3.7.6) to allow candidates to be screened from the match run rather than listed as inactive on the lung waiting list.
19. The Board approved modifications to Policy 3.7.6 (Lung Allocation) et seq. to substitute Functional Status in the Lung Allocation Score (LAS) calculation instead of a New York Heart Association (NYHA) classification since NYHA was not used in the development of the LAS.
20. The Board approved modifications to Policy 3.7.6.4 (Lung Candidates with Exceptional Cases) to clarify that the Thoracic Organ Transplantation Committee may review overrides of Lung Review Board decisions and, if appropriate, refer the matter to the MPSC for further action.
21. The Board approved modifications to Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates) to correct a discrepancy in the policy as to the manner in which heart-lung candidates are registered on the waiting list to reflect the current, simplified registration process of allowing heart-lung candidates to be registered on a heart-lung list rather than registration on separate heart and lung lists.
22. The Board approved three requests for heart waiting time modification.

The Board approved modifications to the committee-sponsored alternative system for assigning priority in the allocation of deceased donor kidneys to intended candidates for living donor kidneys.

The Board granted final approval of modifications to Policy 3.4.6.1 (Application Process for Alternative Organ Distribution or Allocation Systems) that require public comment prior to approval of Alternative Organ Distribution or Allocation Systems.

The Board approved modifications to Policy 3.5.11.5 (Pediatric Kidney Transplant Candidates) that will assign additional points for children in allocating zero antigen mismatched donation after cardiac death (DCD) donor kidneys.

The Board voted to rescind its approval of the ALU for liver allocation in Region 8. In a separate motion, the Board directed the Liver and Intestinal Transplantation Committee to work with Region 8 to broaden sharing and that AAD Systems would be scrutinized by the Liver and Intestinal Transplantation Committee, which would provide its report to the Board by the September Board Meeting. The Board also emphasized that the focus would be on MELD and wait list mortality rather than waiting time.

The Board voted that, as a national policy, that there would no longer be paybacks required or permitted in liver allocation and transplantation. The Board added that this policy would be implemented concurrently with public comment.

The Board directed that serial blood gas analysis data (PaCO₂, Pao₂, and pH) shall be collected at six-month intervals on candidates ages 12 and older registered for lung transplantation.

The Board approved modifications to Policy 3.7.3 (Adult Patient Status) to eliminate the requirement for heart candidates listed at status 1A(b) to be admitted to the listing transplant center and required that specifics regarding the infection site, infection type, and antibiotics used be included in the narrative.

The Board approved modifications to the lung candidate data entry forms to collect supplemental oxygen use as a percentage along with the oxygen delivery method, and automatically convert percentage to L/min using the following formula: 3% per liter per minute after subtracting 21% (room air).

The Board approved modifications to Policies 3.7.10 (Sequence of Heart Allocation) and 3.7.10.1 (Sequence of Adolescent Heart Allocation) that will give higher priority to Status 1A and 1B candidates in local areas and Zone A when those candidates may receive additional post-transplant survival benefit and add a policy for the allocation of hearts recovered from adolescent donors.

The Board approved the recommendation that in conjunction with the approval of the proposed modifications to the heart allocation system that would allow the sharing of hearts to status 1A and 1B candidates prior to local status 2 candidates, any AAD System that alters the definition of local unit (i.e. the OPO) or defines the second level of allocation that is less than Zone A will be dissolved at the time of implementation of the system.

The Board approved new Policy 3.4.6 (Receiving and Responding to Organ Offers) and modifications to Policy 7.5 (Submission of Donor Information) to require that transplant centers must be able to view and respond to organ offer notifications in an electronic manner, and to require that OPOs must be able provide donor information required for organ placement in an electronic data format, for implementation on January 1, 2007.

The Board approved modifications to Policy 2.2 (Evaluation of Potential Donors) to require EBV serology results on all donors to decrease the severity and frequency of PTLD in immunosuppressed EBV negative recipients receiving EBV positive donor organs.

The Board approved revisions to the Bylaws, Article VII (Permanent Standing Committees) to separate the Kidney and Pancreas Transplantation Committee into separate Kidney Transplantation and Pancreas Transplantation Committees, as indicated by the new OPTN Contract.

The Board resolved that the method of listing heart transplant candidates who are part of the VA population and are housed at the VA hospital and listed as Status 1A anticipating transfer to the University Hospital transplant center for transplant surgery and immediate post operative care, which is a variation from the provision in Policy 3.7.3 requiring that a patient listed as Status 1A be “admitted to the listing transplant center hospital,” shall not be considered an alternative allocation system (AAS).

The Board denied the continuation of the Ohio Solid Organ Transplant Consortium alternative allocation/distribution system for lungs.

The Board denied the continuation of the Tennessee Transplant Society alternative allocation/distribution system for lungs.

The Board dissolved the Region 6 alternative allocation/distribution system for lungs.

The Board tabled a proposal to develop a mechanism to assure that documented discussion occurs with potential donor families making a directed donation request regarding the implications of circumventing the existing organ allocation system.

The Board tabled proposed guidance on acceptable relationships for deceased directed donation. Later in the meeting, the Board resolved that deceased directed donation is and should be an infrequent circumstance in the context of a strong pre-existing relationship between the donor / donor's agent and candidate. Any association formed through commercial public solicitation solely for the purpose of receiving a deceased directed donation transplant jeopardizes the principles of equitable organ allocation. The Board further directed that this position shall be communicated to the UAGA drafting committee for their consideration.

The Board approved modifications to Bylaws Appendix A, § 2.06A (Membership and Professional Standards Committee Action) et seq.; Appendix B § I (Key Personnel) et seq.; and Appendix B, Attachment I, Section II (Inactive Program Status), to clarify the options for adverse actions to encourage member compliance.

The Board approved the recommendation that the MPSC establish subcommittees to review, inter alia, proposed methods for MPSC improvement and propose changes to the membership review process and standards, including the possibility of constructing a “whistleblower” provision and developing language such that if a physician is found to be problematic regarding policy compliance, that that physician then be barred from further being, or in the future being a program director or a primary surgeon and physician at a different location, and provide a report to the Board at its March 2006 meeting.

The Board approved the recommendation that the OPTN and SRTR staffs work with the MPSC to develop metrics of assessment and any appropriate corresponding bylaws text to address actions when the metrics are triggered.

The Board requested that HHS issue a Federal Register notice stating that living donor guidelines developed by the OPTN in accordance with the policy development process described in §121.4 of the OPTN Final Rule have the same status as other OPTN policies, and inviting public comment on the matter.

The Board adopted the use of the terms, “kidney paired donations” and “list paired donations” in all OPTN/UNOS matters. Existing bylaw and policy references are to be amended to conform to these terms. The Board also requested that DHHS assist the OPTN in federal legislative efforts to amend NOTA to specifically endorse kidney paired donation and list paired donation, and also to seek supportive language in the report of conferees to accompany the 2006 HHS appropriations and other legislative vehicles, as appropriate.

The Board approved modifications to all OPTN policies in order to make the policies unique to the OPTN and generic as to the OPTN Contractor. The proposed modifications will standardize language within the policies including the usage of terms including candidate, recipient, match system, and waiting list; a definition for UNetsm was added; specific references to UNOS and departments within UNOS were removed in favor of using a generic description of the OPTN Contractor; and UNOS-specific policies were removed.

The Board approved the Slate of Nominees for the election of the members of the Board of Directors for the term beginning at the conclusion of the last regular meeting of the Board of Directors prior to July 1, 2006, as recommended by the Nominating Committee.

The Board approved the recommendation that UNOS prepare and release aggregate statistics on organ acceptances and refusals, with refusal codes, by transplant program and by year from July 2000 onward. These data will be provided if the requestor agrees to pay a reasonable charge for the separable cost of responding to this request.

The Board directed that transplant programs must ask potential living donors for consent to be contacted by the transplant center or UNOS for the purpose of collecting long-term follow-up information, and maintain documentation of this communication with the living donor.

The proposal to adopt the AOPO Recommended definition for “eligible death” as the new UNetsm definition for eligible death was tabled to permit further review and comment from HRSA.