

EXECUTIVE SUMMARY
OF THE MINUTES
OPTN/UNOS
BOARD OF DIRECTORS MEETING
June 23-24, 2005
St. Louis, Missouri

Dr. Metzger called the meeting to order at 8:30 a.m. on June 23, 2005. A quorum was present, and 33 of the Board members were in attendance during the meeting.

The Board appointed Janet M. Shaftel, RN, BSN, to fill the vacancy created by the resignation of Dr. Arnold G. Diethelm, representing the Patient and Donor Representatives on the Board of Directors. The Board also appointed Dr. Sandra Rosen-Bronsen to fill the vacancy created by the resignation of Dr. Charles G. Orosz, representing the Histocompatibility Experts on the Board of Directors.

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 new Policy 3.6.13 (Histocompatibility Testing for Liver Transplantation), providing that a liver transplant program and its histocompatibility laboratory must have a joint written policy that states when histocompatibility testing is necessary.
2. The Board approved modifications to the Bylaws Appendix B – Attachment II (Criteria for Designated Histocompatibility Laboratories) developed at the request of the Membership and Professional Standards Committee to provide formal guidance in assessing directors who oversee multiple laboratories.
3. The Board approved extensive policy modifications to define and provide processes for organ allocation variances and establish more systematic processes for reviewing AAD Systems, both existing and newly proposed.
4. The Board approved modifications to Policy 3.3.3 (Renal Acceptance Criteria) to require all transplant centers to review and update annually the criteria according to which they will accept deceased donor kidneys allocated through the Organ Center.
5. The Board approved modifications to Policy 3.2.4 (Match System Access) to eliminate a provision requiring entry of all renal deceased donor data in the allocation match system by Members within 15 hours of organ recovery.
6. The Board granted final approval, post-public comment, to modifications to Policy 3.6 (Allocation of Livers). These modifications correct and clarify policies related to allocation of deceased donor livers and broaden allocation to the most urgent candidates.
7. The Board endorsed the document entitled *Billing and Reimbursement of Live Organ Donors*, which identifies many of the insurance billing and reimbursement issues

experienced by living donors, and is intended for use as an educational tool for both transplant centers and insurance companies.

8. The Board approved modifications to Policy 3.5.3.3 (Mandatory Sharing) to adjust the approved policy to reflect the intent to exempt regional and nation sharing of zero antigen mismatched DCD kidneys from the requirements of the zero antigen mismatched kidney sharing policy.
9. The Board approved modifications to Policies 3.6.4.1.1 (Adult Patient Reassessment and Recertification Schedule) and 3.6.4.2.1 (Pediatric Patient Reassessment and Recertification Schedule) to allow acceptance of laboratory values obtained within 48 hours for voluntary recertification.
10. The Board approved several membership changes including one new transplant center; eight new programs in existing member centers; twelve pancreas islet transplant programs, and two new independent histocompatibility laboratories.
11. The Board approved requests for new and to renew the membership of non-institutional members (i.e., Medical/Scientific Organizations, Public Organizations, Business, and Individual Members) that desired to continue their membership for another two-year term.
12. The Board approved requests to grant full approval to two programs that now fully meet membership requirements.
13. The Board approved the reclassification of three former consortia members to the Public Organization membership category.
14. The Board approved modifications to Bylaws Appendix A, Section 1.04A (Processing the Application) to clarify the need for applications to contain required letter(s) of reference to be deemed complete prior to review by the MPSC.
15. The Board approved a programming change to UNetsm to allow thoracic transplant programs to use hepatitis serology as a match screening criteria.
16. The Board approved three heart waiting time modification requests, one lung waiting time modification request, and denied of one heart waiting time modification request.
17. The Board approved modifications to Policy 6.3 (Audit) to reflect the current name of the Ad Hoc International Relations Committee in the policy language.
18. The Board approved a request to allow the Texas Organ Sharing Alliance (TOSA) to allocate A₂ and A₂B kidneys from expanded criteria donors (ECDs) to ABO B and O recipients on their waiting list to facilitate more equitable kidney allocation to ABO B and O candidates while minimizing the detrimental effects on ABO A candidates.
19. The Board approved an alternative allocation system for the Alabama Organ Center OPO to allow either of the OPO's kidney transplant centers (the University of Alabama at Birmingham or the University of South Alabama) that imports a kidney to backup the identified potential recipient for whom the kidney was offered with another candidate listed with that transplant center if backup is offered by the sharing OPO. Locally recovered kidneys would be allocated using the existing standard system.
20. The Board approved a request from LifeGift of Texas for an ALU/Variance for split livers. In cases when the liver is initially allocated to an adult recipient, the variance will allow the remaining segment to be transplanted by the surgeon performing the split in another candidate on the transplant waiting list, in order of the center's list.

The Board approved amendments to Policy 3.2.1.8 (Waiting Time Modification) that provide for expedited review of waiting time adjustments submitted on behalf of pediatric kidney transplant candidates, with review of such adjustments at the next meeting of the full Kidney and Pancreas Transplantation Committee.

The Board considered but declined to approve modifications to Policies 3.7.10 (Sequence of Heart Allocation) and 3.7.10.1 (Sequence of Adolescent Heart Allocation). This proposal would have given higher priority to Status 1A and 1B candidates in local areas and Zone A when those candidates may receive additional post-transplant survival benefit. The Board charged the Thoracic Organ Transplantation Committee to address certain questions raised regarding this proposal and submit its responses to the Executive Committee.

The Board approved modifications to Policy 3.7.6 (Lung Allocation) and Policy 3.7.9 (Time Waiting for Thoracic Organ Candidates) that modify the data entry fields and candidate variables, as well as assign Lung Allocation Scores in certain situations; provide for exceptional case review; and clarify that the earliest date and time of each candidate's most recent update in UNetsm will be used to break tied Lung Allocation Scores, and provide for the inactivation of candidates with Lung Allocation Scores of zero due to missing data variables. The Board specifically approved an amendment to this proposal to provide for transplant programs' ability to override Lung Review Board decisions, with automatic peer review of the override.

The Board approved modifications to Policy 3.5.11.3 (Panel Reactive Antibody) to specify that in order for kidney transplant candidates to receive four points for sensitization levels of 80% or more, HLA antigens against which the candidate has antibodies must be specified on the waiting list. In the same vote, the Board approved for public comment and evaluation by the MPSC a proposal that programs that transplant high-PRA patients at a level that is two standard deviations above the national average will be flagged for review in order to identify best practices or the potential for a violation of Policy 3.5.11.3.

The Board approved new Policy 5.8 (Vessel Recovery, Storage, and Transplant) to provide guidance for the recovery, use, and storage of deceased donor vascular allografts and set a requirement that the transplant center must designate a person to maintain and disseminate appropriate records of vessel usage.

The Board approved an amendment to Bylaws Article IX, Section 9.2 (Regional Review Boards) to specify that only physicians and surgeons who are active in the field of organ transplantation corresponding to the organ-specific Review Board may be voting members on the Regional Review Boards, and that non-physicians and public representatives may continue to serve as non-voting members of Regional Review Boards.

The Board directed the distribution of a potential donor screening questionnaire to the Ad Hoc Living Donor and Patient Affairs Committees for consideration in assessing potential medical risks for living donors.

The Board resolved to begin developing a nationwide mechanism for allocating organs from non-directed live donors.

The Board resolved to develop comprehensive, donor-centric information to support prospective and actual living organ donors, and establish that the OPTN/UNOS will not participate in the solicitation of living donors on behalf of specific candidates.

The Board resolved to encourage transplant centers and OPOs to inform prospective live donors regarding the principles of the allocation system.

The Board approved modifications to Policy 2.2 (Evaluation of Potential Donors) to require EBV serology results on all donors.

The Board directed that the Liver Regional Review Board (RRB) Chair must be notified of RRB members who have not voted within 7 days of submission of an exceptional case application.

The Board directed that live-donor deaths and failure of the live-donor donated organ within the first six months post-transplant are events that will be reported to the MPSC for further review and reporting to the Board.

The Board approved modifications to Policy 3.7.6.3 (Candidate Variables in UNetsm) to allow missing heart catheterization values to default to normal pulmonary pressure values.

The Board approved the serial collection of blood gas analysis data on lung transplant candidates ages 12 and older.

The Board declined to approve a proposal to designate thoracic program representation on the Executive Committee but instead, directed that the Executive Committee contain representatives of all three major organ systems (i.e., Kidney-Pancreas; Liver-Intestine; and Thoracic organ systems).

The Board approved the recommendation that candidate and recipient home address information be added to TCR and TRR forms with automatic transfer of the data to the TRF forms for the duration of the Data Working Group's proposed SF-36 quality of life pilot study (approximately 3 years).

The Board resolved to modify the current Board and committee meeting cycles such that the Board will now meet 4 times annually. The organ specific committees will meet on staggered nine-month cycles and will report to the Board every nine months. The Membership and Professional Standards Committee (MPSC) will report to the Board at every Board meeting while the remaining committees will also meet on nine month cycles and will report to the Board at the appropriate meeting based on the activities undertaken by the committees.

The Board revised the approach to OPTN policy development, implantation, and monitoring such that the Board will consider for approval only those proposals that include complete computer programming specifications and information regarding the resources that will be required to implement, maintain, communicate, monitor, and evaluate (post-implementation) the policy.

The Board approved the approach whereby all pancreas islet candidates will start with a zero count for total infusions on the day that the relevant modifications to the computer system are implemented.

The Board approved modifications to Policy 3.4.6.1 (Application) to specify that all applications for alternative organ distribution or allocation systems shall be submitted for public comment and then reconsidered by the relevant committees prior to Board consideration of the application.

The Board directed that a system for simultaneous, electronic organ offers and responses be developed and implemented by January 1, 2007.

The Board approved modifications to Bylaws Article VII, Section 7.1 (Enumeration of Committees) to change the status of both the Ad Hoc Operations and the Ad Hoc Living Donor Committees to permanent standing committees.