

**EXECUTIVE SUMMARY  
OF THE MINUTES**

**OPTN/UNOS**

**BOARD OF DIRECTORS MEETING**

**June 28-29, 2001**

**San Diego, California**

Dr. Adams called the meeting to order at 8:30 a.m. on June 28, 2001. A quorum was present, and 35 of the Board members were in attendance during the meeting.

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 the recommendation that there should be only one Unacceptable Antigen Equivalence Table to be used for all organs, and this table should be the one that is currently used for kidney and pancreas organs. The table currently used for thoracic, liver and intestine organs will be removed.
- 2) The Board approved the proposal establishing a general rule specifying who may select between donor kidneys when both the right and left kidneys are available for transplantation.
- 3) The Board approved the recommendation that, in a manner analogous to that employed for other solid organs, pancreases should be procured and allocated for either islet or whole pancreas transplantation, and an islet waiting list should be maintained and islet recipient outcomes monitored.
- 4) The Board approved proposed policy language clarifying the sequence of allocation for adult cadaveric livers accepted for segmental transplantation and providing a structure for equitably allocating split livers to potential donors.
- 5) The Board approved the proposed national voluntary variance to provide a clinical framework for testing the efficacy of transplanting A<sub>2</sub>/A<sub>2</sub>B kidneys into blood group B recipients. It is also anticipated that the proposed renal allocation variance will increase the availability of donor organs for blood group B recipients.
- 6) The Board approved the proposal eliminating the priority assigned to phenotypic identity for allocating zero antigen mismatched kidneys when there are multiple zero antigen mismatched candidates identified in the matchrun for a single donor, and requiring that allocation of these organs be based on waiting time at each level of sequence to which this priority had been previously applied.
- 7) The Board approved the proposed language modification to Article VI of the By-Laws (Permanent Standing Committees) adding the Data Advisory Committee and deleting the Scientific Advisory Committee.
- 8) The Board approved the recommendation to relocate Policy 10.5 language (Reporting Data to the Scientific Advisory Committee) to new Policy 7.3 (Reporting Data to the OPTN) in addition to other modifications to Policy 7.0 (Data Submission Requirements).
- 9) The Board approved the recommendation that Policy 3.5.1 (ABO "O" Kidneys Into ABO "O" Recipients and ABO "B" Kidneys Into ABO "B" Recipients) be applied to variances, sharing arrangements and alternative local units in addition to the standard system for kidney allocation.

- 10) The Board approved seven requests for waiting time modification and declined to approve one request for waiting time modification, as recommended by the Kidney and Pancreas Transplantation Committee.
- 11) The Board approved the modification to the standard template for the pancreatic islet waiting list field in UNet<sup>sm</sup> (Donor Acceptance Criteria) to request “Acceptance of HCV positive donor organ?,” followed by prompts for yes or no.
- 12) The Board approved the recommendation requesting that UNOS staff prioritize programming for liver allocation first for Status 1 sharing agreements, followed by any other sharing agreements or programming that directly impact patient prioritization, then by other programming changes.
- 13) The Board approved the recommendation to exclude the votes of Regional Review Board members when voting on cases originating from their transplant centers.
- 14) The Board approved modifications to Policy 3.6.5.1 (Re-execution of Liver Match) specifying that any re-execution of the liver match system for the same donor within eight hours of the original match for reasons other than those stated in the policy must be retrospectively reviewed by the Regional Review Board.
- 15) The Board approved policy modification language that would require that the UNOS Waiting Time Modification Form be included as supporting documentation when requests for waiting modifications are made.
- 16) The Board approved the modification to the Regional Review Board guidelines to grant the Regional Review Board chair the authority to remove a non-responding program from having representation on the Regional Review Board and to provide that such programs will be referred to the Liver and Intestinal Organ Transplantation Committee.
- 17) The Board approved recommendations for new transplant centers, new transplant programs, new laboratories, new public members, public member renewals, and program status changes.
- 18) The Board approved the recommendation that UNOS discuss with HCFA and other appropriate agencies the effects of non-coverage of specific non-immunosuppressant, prophylactic medications and the subsequent effect of not being listed for transplant or losing valuable waiting time if placed on hold.
- 19) The Board approved the recommendation requiring that the list of data variables be submitted for each patient at the time of listing for a lung transplant and that the variables be resubmitted every six months.
- 20) The Board approved the recommendation that all listings under adult status 1A criterion (b) be sent to the Regional Review Board for clinical review.
- 21) The Board approved the Bronchoscopy Survey to collect information on lung procurement practices.
- 22) The Board approved amendments to the Heart Status 1A Justification Form requiring validation of patient admission.
- 23) The Board approved the recommendation allowing the 30-day clock for all patients requiring a second VAD placement within the first 30 days of their Status 1A listing be restarted.
- 24) The Board approved the recommendation allowing Regional Review Board chairs to send letters of warning to non-responding Regional Review Board members and allowing the local Regional Review Board members to remove non-responding members by vote.
- 25) The Board approved the request from LifeSource Upper Midwest OPO to modify its variance for pancreas allocation.
- 26) The Board approved the variance allocation from the University Hospitals of Cleveland and Cleveland Veterans Affairs Medical Center.

The Board approved the recommendation regarding sharing of zero antigen mismatched kidneys that would eliminate requirements for sharing kidney/pancreas combinations for zero antigen mismatched patients unless the patient is highly sensitized (PRA greater than or equal 80%).

The Board approved recommended policy language providing that, in cases where unanimity cannot be achieved at the local level, submission of applications for variances, sharing arrangements, or ALUs no longer require unanimous agreement from all participants, and such applications may be submitted with a minimum of 75% participation of the parties involved.

The Board approved the proposed Region 5 Status 1 Liver Sharing Agreement designed to facilitate the sharing of livers of critically ill patients in Region 5.

The Board approved the recommendation that UNOS proceed with programming of the Model for End Stage Liver Disease (MELD) and the Pediatric End Stage Liver Disease (PELD) for liver allocation with refinement in November and then implementation.

The Board approved the proposal that, for purposes of prospectively validating the PELD Risk Scoring System, relevant data will be collected on all pediatric liver patients listed for liver transplantation as of the start of the validation study, in addition to patients who are newly listed, removed from the waiting list, and change status.

The Board approved the recommendation to delete policy language providing that a patient determined eligible for receipt of four points for donation status may retain these points for determining priority for allocation of donated kidneys in the event of subsequent renal insufficiency in qualification as a transplant candidate, or transfer the points to the recipient of the donated organ in the event the recipient is relisted for transplantation. In addition, the Board approved the recommendation that points transferred pursuant to this language that has now been deleted would not be altered by this action.

The Board tabled the proposed recommendation regarding routine HLA typing or crossmatching for liver transplantation.

The Board approved the recommendation to support the development of qualifications for organ recovery personnel by the AST and would support a policy development process that would include UNOS, ASTS, AOPO and other affected parties.

The Board approved the proposed local patient listing mechanism to facilitate collaboration between the National Institutes of Health and the Washington Regional Transplant programs.

The Board adopted the position that UNOS has always condemned the brokering of organs and supports the present US law that prohibits the buying and selling of organs. Therefore, UNOS members should take appropriate actions to prevent participation in brokered arrangements wherever they may occur for the purchase or sale of organs, and UNOS members who participate in such arrangements shall be considered for status as “member not in good standing.”

The Board approved, in principle, a modification in the algorithm for lung distribution from time on the waiting list as the predominant determinant of allocation to relative risk of mortality on the waiting list balanced by probability of one year survival post transplant.

The Board approved, in principle, the recommendation that heart allocation be based upon a model of the projected risk of mortality on the waiting list balanced by the projected post transplant survival, and that the data variables needed to make that determination will be prospectively collected.

The Board approved the recommendation to not submit the proposal regarding modifications of alternative distribution units in heart allocation for public comment pending development of the model and to continue severity illness score for heart allocation.

The Board approved the recommendation that Heart Status Justification Forms for Status 1A listing extensions for Adult Status 1A (a) and (c) and Pediatric Status 1A (a), (b) and (c) patients be reviewed by UNOS staff only and that the requirement for clinical narratives for these patients for Status 1A listing extensions be removed, and that the Status 1A Justification Forms be modified accordingly. In addition, the Board approved the position that the Thoracic Regional Review Boards shall retain the authority to review all Status Justifications Forms for thoracic patient listings and extensions, and in cases where the review of specific categories of Thoracic Status Justification Forms is delegated to UNOS staff, the review by UNOS staff does not involve the exercise of medical judgement and is limited solely to objective review of the Status Justification Form to determine completeness.

The Board approved the recommendation that the SRTR contractor should be requested to conduct an ongoing study through the OPTN Kidney and Pancreas Transplantation Committee to cross reference multiple data bases on an ongoing basis with the intent of assembling data appropriate to assess long-term living donor risk following organ donation. The study results are intended for use by the OPTN committees in formulating policy recommendations.

The Board approved the proposal from the Regional Organ Bank of Illinois to modify its variance for kidney allocation.

The Board approved recommended modifications to Policy 9.0 (Release of Information to the Public) so that the language more substantially coincides with regulatory and contractual provisions.

The Board approved recommended modifications to Policy 10.0 (Access to Data) so that the language more substantially coincides with regulatory and contractual provisions.

The Board approved, for public comment, amendments to Policy 7.8.1 (Data Submission Standard) requiring 95% of expected forms completion within three months and 100% of expected forms completion within six months of the due date.

The Board approved, for public comment, By-Law language modifications regarding the transplant physician requirements.

The Board approved the recommendation to produce and distribute organ specific transplant information to various professional organizations, national meeting participants and other professional groups.

The Board approved the recommendation to engage in a dialogue with the United States Surgeon General concerning the seemingly epidemic proportions of patients developing diseases which often lead to organ failure.

The Board endorsed specific activities of the Transplant Administrators Committee including assisting financial coordinators in their understanding of insurance issues.

The Board endorsed follow-up efforts by appropriate committees to determine the effect of the establishment of the role of financial coordinator; a better definition of the role of the financial coordinator; and determining compliance with the financial coordinator requirements.

The Board approved the recommendation to request that HHS address the issue of the Indian Health Service not paying for organ acquisition charges for Native Americans who do not have other health insurance coverage for transplantation.

The Board endorsed the recommendation to task all committees to estimate what proportion of medically suitable transplant candidates are denied access to transplantation due to the lack of adequate insurance coverage or their inability to pay for the transplant itself and/or medications including those candidates who have lost their insurance coverage.

The Board endorsed the recommendation to appoint a delegation to explore with various groups a strategy in approaching the pharmaceutical industry to expand patient access to drug assistance programs.

The Board approved the proposal to recommend that HHS publish a RFP to study the cumulative effects of socioeconomic concerns that affect access to transplantation.

The Board approved the recommendation that the OPTN/UNOS Board of Directors, in collaboration with HRSA, explore the availability of necessary resources in a timely manner to implement the Patient Access Task Force recommendations approved by the Board of Directors.

The Board approved proposed modifications to the UNOS Liver Status Regional Review Board Operational Guidelines to allow Liver Regional Review Boards (by a 2/3 vote of the Review Board) the discretion to authorize UNOS staff to review all Status 1 and Status 2A standard cases, defined as cases in which the submitted justification form meets all objective criteria for the specified status. The standard case review by UNOS staff does not involve the exercise of medical judgement and is limited solely to objective review of the justification form to determine completeness.

The Board approved the Preliminary Plan for the implementation of MELD and PELD.

The Board approved the recommendation to reduce the Registration Fee for listing a potential recipient on the patient waiting list to \$384 from the previous Registration Fee amount of \$404.

The Board approved the 2002 OPTN Operating Budget.

The Board approved the revised Region 8 sharing agreement for Status 1 liver patients.

The Board approved the modifications to New England Organ Bank's variance for liver allocation.

The Board endorsed the draft letter to Secretary Thompson conveying the conclusions reached at the OPTN Planning Meeting on June 12, 2001.

The Board approved the recommendation that the policies be incorporated into the By-Laws to satisfy certain requirements of Virginia corporate law.