

**EXECUTIVE SUMMARY
OF THE MINUTES**

UNOS/OPTN

BOARD OF DIRECTORS MEETING

November 16-17, 2000

Washington, DC

Dr. Adams called the meeting to order at 10:00 a.m. on November 16, 2000. A quorum was present, and 37 of the Board members were in attendance during the meeting.

The Board elected John R. Lake, M.D. to fill the vacancy created by the resignation of John F. Neylan, III, M.D., representing the Medical/Scientific Organizations, and the Board elected Robert A. Bray, Ph.D. to fill the vacancy created by the resignation of Alan Ting, Ph.D., 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 amended language for Policy 3.5.1 (ABO "O" Kidneys Into ABO "O" Recipients) to also provide for ABO "B" Kidneys Into ABO "B" Recipients.
- 2) The Board approved recommended revisions to Policies 3.7.3 and 3.7.4 (Adult and Pediatric Patient Status-Heart) requiring a Regional Review Board conference call for approval of Status 1A extensions beyond fourteen days for adult Status 1A patients in a specific category and pediatric patients in a separate specific category.
- 3) The Board approved the recommendation that the publication of pre-transplant survival outcomes be postponed until appropriate risks adjustments of these data have been implemented.
- 4) The Board approved recommended guidelines regarding non-heartbeating donation.
- 5) The Board approved recommended By-Law amendment language addressing the preservation of zero antigen mismatch tissue typing materials.
- 6) The Board approved amendment language to Policy 3.5.2.3 (Mandatory Sharing) and Policy 3.5.4.2 (Kidney Payback Debt Limit) to clarify the revised priority of low PRA patients listed with OPOs that are owed a payback kidney and that exceed the short term or long term payback debt thresholds.
- 7) The Board approved three requests for waiting modifications and declined to approve two requests for waiting time modifications, as recommended by the Kidney and Pancreas Transplantation Committee.
- 8) The Board approved recommendations regarding new transplant centers, new transplant programs, public member renewals, and program status changes, as recommended by the Membership and Professional Standards Committee.
- 9) The Board approved By-Law amendment language deleting redundancies in the kidney and heart transplant physician requirements.
- 10) The Board approved the recommended language modification regarding standard organ package specifications to eliminate the requirement that a rigid container be used when transporting lungs.
- 11) The Board approved further language modifications regarding standard organ package specifications eliminating the requirement that peripheral blood samples be kept at ambient temperature during transportation.

- 12) The Board approved language modifications regarding organ procurement quality to require that additives to flush solutions are documented during the organ retrieval process.
- 13) The Board approved modifications to Policy 3.6 (Allocation of Livers) to assign preference in all allocation of pediatric donor livers to pediatric liver transplant candidates within medical urgency statuses and the standard (or approved alternative) distribution areas for liver allocation are to be applied to all UNOS members, regardless of whether they operate with an approved variance, sharing arrangement or alternative local unit for liver allocation/distribution.
- 14) The Board approved language modifications to Policy 3.6.5.1 (Execution of the Liver Match System) that prevents subsequent re-execution of the liver match system for the same donor without appropriate justification to provide that this policy would not apply to re-allocation of a split liver graft.
- 15) The Board approved a recommendation addressing inquiries for the acceptance of segmental livers incorporating appropriate defaults if no response is given for a particular patient.
- 16) The Board approved the recommendation that Status Justification Forms for patients listed as 1A under certain criteria be submitted for UNOS staff review only while requiring that patients listed for Status 1A under different criteria continue to require review by the appropriate Regional Review Board.
- 17) The Board approved the proposal from the Washington Regional Transplant Consortium to modify its variance for pancreas allocation with implementation pending certain clarifications and receipt of all necessary signatures.
- 18) The Board approved the proposal from the California Transplant Donor Network to modify its variance for kidney allocation.
- 19) The Board approved two separate proposals from Carolinas Medical Center/Lifeshare of the Carolinas to allocate kidneys using a variance and to allocate pancreases using a variance.

The Board approved proposed By-Law amendment language addressing the notification of patients upon completion of their evaluations as a candidate for transplantation or upon their removal from the patient waiting list as a transplant candidate for reasons other than transplantation or death. The amendment language also established a time limit of ten business days for providing these patient notifications and required transplant programs to maintain documentation of these notifications.

The Board approved the recommendation that the MELD system be prospectively validated against the current liver transplant patient waiting list prior to implementation for the purpose of liver allocation and that this evaluation be undertaken concurrently with submission of the MELD system to DHHS for consideration as proposed modification to Policy 3.6 (Allocation of Livers). The recommendation also provided that the implementation of the MELD system as allocation would not occur prior to completion of both the DHHS review of the policy proposal and the validation study.

The Board also approved specific language modifications to Policy 3.6 (Allocation of Livers) replacing the current Status 2A, Status 2B, and Status 3 Medical Urgency categories with a continuous numerical scale which determines a patient's risk of mortality on the waiting list for submission to DHHS and for public comment concurrently.

The Board approved the recommendation that data to determine creatinine clearance based on the Cockcroft-Gault formula should be collected on all Status 2A and 2B liver transplant candidates and compared with serum creatinine as a predictor of liver transplant patient survival on the waiting list.

The Board approved the recommendation that the PELD scoring system be approved for pediatric patients. In addition, the priority of pediatric liver candidates for pediatric liver donors currently specified in Policy 3.6 will be maintained under the proposed scoring systems for pediatric and adult liver candidates such that within each risk score a liver recovered from a pediatric organ donor would be allocated to a pediatric liver candidate before the liver would be allocated to an adult candidate.

The Board adopted the position that, at the present time, there is not a consensus on what benefit would be derived by redrawing the allocation distribution units, and the Board encouraged the regions to continue to develop broader sharing mechanisms for all patients. In addition, it was determined that until such time as the MELD system is implemented, it would be premature to make any recommendations regarding allocation distribution because it is likely that the MELD system will have a greater impact on directing organs to patients most in need.

The Board approved the recommendation regarding the public release of updated OPO specific kidney payback data that would allow publication of kidney payback debt and credit information by OPO, without permission from the member.

The Board approved the proposal and sample protocol establishing a process to assist transplant centers in accepting and allocating living donor organs provided as altruistic gifts for the benefit of unspecified patients on the waiting list.

The Board adopted the position that the current systems of kidney and kidney/pancreas work well to allocate organs equitably, addressing all aspects of the Final Rule for the operation of the OPTN and approved the recommendation that the report on kidney and kidney/pancreas allocation prepared by the Kidney and Pancreas Organ Transplantation Committee be submitted to HRSA in compliance with the Final Rule and that the systems of kidney and kidney/pancreas allocation be continued without further modification at this time. The Board noted that the OPTN would continue to evaluate the systems and make further modifications to promote justice while preserving utility.

The Board declined to approve the proposal for New Mexico to relocate from Region 5 to Region 4.

The Board approved the recommendation that UNOS policy addressing application, review, dissolution and modification processes for alternate organ distribution or allocation systems, as modified, be approved for submission to DHHS and for public comment concurrently.

The Board approved proposed policy language modifications addressing liver transplant candidates with Hepatocellular Carcinoma (HCC) incorporating the MELD system for these patients, for submission to DHHS and concurrently for public comment.

The Board approved submitting existing heart allocation policies to DHHS, and the Board approved submitting existing lung allocation policies to DHHS as an interim measure, with the intent that risk stratification for lungs be developed when data are available.

The Board approved the recommendation that each committee includes in future reports to the Board of Directors, its deliberations and proposed resolutions on patient access issues. The Board also approved the recommendation that each OPTN committee reviews standard minimum listing criteria to determine the effects, if any, on equitable access to transplantation.

The Board adopted the position that simulation modeling is a useful and valuable tool for the purpose of developing organ allocation policies, provided that prior to implementation, allocation according to the model is shown to be validated by current data, and beginning at two years after any policy revisions based upon modeling, model projections are compared with actual data.

The Board approved the recommendation that the Potential Transplant Recipient Form must be submitted to the OPTN within 15 days of the matchrun date by the OPO or the Organ Center for each cadaver donor organ that is offered to a potential recipient.

The Board approved the recommendation that all OPOs be required to utilize the UNOS shipping label, or in the alternative, the OPOs may produce a shipping label with the essential information, including the biohazard symbol, from the UNOS label.

The Board approved proposed By-Law language modifications providing that a UNOS member laboratory may engage another laboratory to perform testing by subcontracting the work of that laboratory if the subcontracting laboratory is CLIA certified/exempt and either a UNOS member laboratory or ASHI accredited in the category and approved for the method(s) which cover the referenced testing.

The Board approved the Region 7 liver sharing agreement and variance for Status 1 transplant candidates.

The Board approved additional policy modification language addressing application, review, dissolution and modification processes for alternative organ distribution or allocation systems to include that applications must address the considerations stated in §121.8 (a) and (g) of the Final Rule as well as comply with other application requirements as may be established by the appropriate committees and Board of Directors.

The Board approved a proposed By-Law language modification increasing the maximum number of Board members from 40 to 41. The Board also approved the revised Board Composition Plan for the term beginning at the conclusion of the last regularly scheduled meeting prior to July 1, 2001.

The Board approved the slate of nominees for election of members to the Board of Directors for the term beginning at the conclusion of the last regularly scheduled meeting of the Board of Directors prior to July 1, 2001.