

EXECUTIVE SUMMARY

OF THE MINUTES

OPTN/UNOS

BOARD OF DIRECTORS MEETING

November 20-21, 2003

Richmond, Virginia

Dr. Wiesner called the meeting to order at 8:00 a.m. on November 20, 2003. A quorum was present, and 36 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 additions to Policy 7.1 (Reporting Definitions) that will support and clarify expectations for length of follow-up on living donors and for the timeliness of collecting patient data for submission.
2. The Board approved amendments to data elements in the UNetsm Potential Transplant Recipient (PTR) data collection screen to enhance data collection. Changes shall be implemented upon approval by the Office of Management and Budget.
3. The Board approved modifications to Policies 3.5.11.1 (The Point System for Standard Donor Kidney Allocation – Time of Waiting) and 3.5.12.1 (The Point System for Expanded Criteria Donor Kidney Allocation – Time of Waiting) to combine the Waiting Time Qualification Form with the Kidney Candidate Listing Form on-line so that verification of patient medical criteria must be completed and submitted electronically before waiting time accrues which will alleviate some of the administrative burden for the transplant centers and ensure that waiting time is accrued after all medical criteria have been submitted at the time of listing.
4. The Board granted final approval to modifications to Policy 3.6.4.7 (Combined Liver-Intestine Candidates) that would assign patients awaiting a combined liver-intestine transplant who are registered on both waiting lists an increase in their MELD/PELD score equivalent to a 10% risk of 3-month mortality.
5. The Board approved the recommendation to replace “incentive” with “benefit” when discussing ways of offering financial or other assistance to encourage individuals to become donors and to show appreciation for those who are donors.
6. The Board approved modifications to Policy 7.5 (Submission of Donor Information) stating that all living donors must be registered with UNOS via the Living Donor Feedback Form prior to surgery.
7. The Board directed that the Living Donor Six-Month Quality of Life Survey be sent from UNOS directly to the living donor.
8. The Board approved the Living Donor Six-Month Quality of Life Survey.

9. The Board approved modifications to Appendix C to Policy 3.0 (Resolving Discrepant Donor and Recipient HLA Typing Results in the OPTN Database) to allow the display of the typing laboratory's and OPO's identifier.
10. The Board approved modifications to the pancreatic islet match algorithm to specify, on either a center- or patient-specific basis, at the option of the center, whether pancreatic islets will be accepted on a local only, local and regional only or a local, regional and national basis.
11. The Board extended the deadline for reducing long-term ABO AB kidney payback debts by two years for those OPOs that have such outstanding ABO AB long-term debts.
12. The Board approved modifications to Policy 3.6.4.5 (Liver Candidates with Exceptional Cases) that would maintain a patient's approved MELD/PELD score if the center enters the extension application more than three days prior to the due date, and the RRB does not act prior to that date.
13. The Board approved new transplant centers, new transplant programs, a new tissue typing laboratory for membership, as well as changes in program status, and renewal of public members.
14. The Board approved one request for lung waiting time modification.
15. The Board approved one request for heart waiting time modification.
16. The Board approved modifications to Policy 3.7.3 Section 1A(c) (Adult Patient Status) to clarify that mechanical ventilation must be continuous for a patient to qualify under Status 1A(c).
17. The Board approved modifications to the Living Donor Registration and Six-Month/Annual Follow-up Forms.
18. The Board approved an international organ exchange arrangement between Life Alliance Organ Recovery Agency and the Commonwealth of the Bahamas.
19. The Board approved an international organ exchange arrangement between New England Organ Bank and King Edward VII Memorial Hospital of Bermuda.
20. The Board approved the LifeSource Upper Midwest Organ Procurement Organization, Inc.'s request for an alternative system for pancreas allocation, effective pending (1) confirmation of Regional approval and (2) programming on the UNOS system.
21. The Board approved the continuation of the Ohio Solid Organ Transplantation Consortium Alternative System for Hearts and Heart/Lungs.

The Board created a generic alternative system that would provide priority in the kidney allocation system for original intended candidates of living donor kidneys who are incompatible with their living donors due to crossmatch results or ABO blood type, when the living donors donate to candidates on the list of patients waiting for deceased donor kidneys. The intent is to facilitate kidney donation by living persons and increase the availability of organs for transplantation overall, effective upon programming on the UNOS System. In this generic alternative system, the term "candidate" shall be used instead of the term "recipient."

The Board initially declined to approve a committee-sponsored alternative allocation system that would permit kidney waiting time accrual to commence for primary transplant candidates, from the time of initiation of chronic maintenance dialysis once listed as an active transplant candidate even if this time pre-dates the day of listing, and for repeat transplant candidates, from the date the candidate returns to chronic maintenance dialysis after graft failure once re-listed even if this

time pre-dates the date of re-listing. The Board reconsidered and rescinded this proposal later in the meeting and instead, approved the development of a voluntary pilot study to assess the impact on kidney allocation from permitting waiting time accrual using the time of initiation of chronic maintenance dialysis once listed as an active transplant candidate, as described above and incorporating administrative requirements from the committee-sponsored alternative allocation system proposal. In addition, the study was amended to include a corresponding study on improved education of patients by physicians when referring those patients for transplantation.

The Board approved the recommendation to communicate to the Centers for Medicare and Medicaid Services (CMS) that access, both from dialysis to the wait list and from the wait list to transplantation, is a significant challenge and concern, and that CMS through its oversight over dialysis facilities and nephrologists is in a position to and should give immediate attention to resolving the challenge.

The Board approved modifications to By-Law, Appendix B (Criteria for Institutional Membership), Section III (Transplant Programs) to ensure that pancreatic islet transplants are being performed at qualified transplant centers.

The Board directed that pancreatic islet transplant programs approved under existing criteria to perform pancreatic islet transplantation must apply under the criteria contained in By-Law, Appendix B (Criteria for Institutional Membership), Section III (Transplant Programs), (C)(4) (Pancreatic Islet Transplantation), effective pending approval of the new criteria by the Board of Directors.

The Board directed that all pancreatic islets allocated for patient clinical transplantation must be allocated through the OPTN/UNOS approved allocation system. The pancreata initially allocated for research cannot be used for clinical organ transplantation without being re-allocated through the OPTN/UNOS approved allocation system.

The Board directed that the transplant center report outcome information to the OPTN/UNOS for each pancreas allocated for islet transplantation to include (1) initial outcome of the pancreas processing/islet isolation; and (2) appropriate follow-up of the recipient. The OPTN/UNOS will work with the Kidney and Pancreas Transplantation and Data Advisory Committees to develop reporting mechanism for these two issues.

The Board initially approved modifications to Policies 3.8.1 (Pancreas Organ Allocation), 3.8.1.4 (Islet Transplantation), and 3.8.1.5 (Islet Allocation Protocol) to facilitate the availability of pancreatic islets to assist in demonstrating the efficacy of islet transplantation as a treatment for diabetes and update the islet allocation protocol to better reflect current science and practice. However, the modifications to Policy 3.8.1.5 (Islet Allocation Protocol) were reconsidered and rescinded later in the meeting. In its place, the Board approved modifications to provide that the allocation of pancreata for islet transplantation shall be to the most medically suitable candidate based upon need and length of waiting time in order to allow for the application of medical judgment and to avoid islet wastage.

The Board directed that the foregoing modifications to Policies 3.8.1 (Pancreas Organ Allocation), 3.8.1.4 (Islet Transplantation), and (Islet Allocation Protocol) shall be applied to OPOs operating with OPTN/UNOS approved alternative systems for allocating pancreata as well as the national system of pancreas allocation; provided, however, that OPOs shall be invited and given time to resubmit their application for an alternative system if they elect to continue their islet alternative allocation protocol.

The Board granted final approval to modifications to Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)) that would eliminate the additional priority assigned to patients with Stage T1.

The Board modified Policies 3.6.4.4.1 (Adult Patient Reassessment and Recertification Schedule) and 3.6.4.2.1 (Pediatric Patient Reassessment and Recertification Schedule) to allow patients with an uncertified MELD/PELD score to be reassigned to a MELD/PELD score of 6.

The Board approved for implementation the updated MELD mortality risk curve in the existing liver allocation algorithm.

The Board deferred implementation of the updated PELD mortality risk curve in the existing liver allocation algorithm pending additional consideration by the Liver and Intestinal Organ and Pediatric Transplantation Committees.

The Board granted final approval to modifications to Policies 3.7.2 (Geographic Sequence of Organ Allocation), 3.7.10 (Sequence of Heart Allocation), and 3.7.11 (Allocation of Lungs) that modify the geographic sequence of allocation for all thoracic organs.

The Board approved modifications to By-Laws, Appendix B, Attachment 1 (Standards for Histocompatibility Testing), Section I (Other Organ Transplantation) to HLA type all transplant recipients and donors when requested by a physician or other authorized individuals; and the laboratory must be capable of performing a prospective crossmatch and must do so when requested by a physician or other authorized individuals.

The Board approved modifications to Policy 3.1.2 (Transplant Center) to state that it is the responsibility of the transplanting surgeon at the transplant center receiving the organ offer for the surgeon's patient to ensure medical suitability of donor organs for transplantation into the potential recipient, including compatibility of donor and patient by ABO blood type.

The Board approved modifications to By-Laws, Section IV (Live Donor Transplant Programs) to require surgical expertise for live liver donor transplant programs to have occurred within the prior 5-year period.

The Board voted to delay approval and implementation of By-Law amendments relative to live donor kidney transplant programs until changes proposed by the Kidney and Pancreas Transplantation Committee and the Ad Hoc Living Donor Committee can be consolidated and finalized by the committees.

The Board declined to approve modifications to Policies 3.2.2 (Multiple Listing Permitted), and 3.2.2.1 (Waiting Time Transferal) that would have restricted multiple listing such that transplant candidates who are multiple listed but do not meet certain defined conditions may remain multiple listed until they are transplanted or removed from the list. Since the Board declined to restrict multiple listing, a resolution supporting the current multiple listing policy was withdrawn.

The Board directed that every transplant program must inform every patient about the options of multiple listing, transferring primary waiting time, and the option to transfer his or her care to another transplant center without loss of accrued waiting time, during the evaluation process and maintain documentation that this was done and provide the patient written material on these options.

The Board directed that every transplant program that does not accept multiple listed patients and/or does not allow these patients to transfer their primary waiting time to that center if the patient so desires, must fully inform the patient during his or her evaluation or sooner.

The Board directed the development of a system within Unetsm that would inform centers that a patient is multiple listed, but not disclose the name of the other center(s) at which the patient is also listed.

The Board directed the development of a system within Unetsm that would notify transplant centers when a multiple listed patient has been transplanted at another center so that he or she can be removed from all other centers' waiting lists so as not to delay organ placement.

The Board directed the Kidney and Pancreas Transplantation Committee to study further and develop an allocation system to offer blood group A₂ (non-A₁) kidneys to blood group B candidates.

The Board directed all OPTN/UNOS committees to investigate further ways to assist biologically disadvantaged patients.

The Board directed the appropriate OPTN/UNOS committees to consider allocation policies that would award points for lower PRA values after a 6-antigen match allocation; encourage laboratories to identify all unacceptable HLA antigens for a sensitized patient; and apply a computer assisted matching algorithm that is based on CREGs to identify patients with the highest predicted probability of a negative crossmatch.

The Board declined to form a Task Force to review institutional multiple listing.

The Board approved the proposed OPTN Charter and By-Laws effective May 1, 2004, that establish organizational documents for the OPTN and further implement various aspects of the OPTN Final Rule.

The Board endorsed the initiatives described in “A Proposal to Increase Organ Donation,” which include a proposal to reimburse wages lost by living donors and to extend coverage under the Family Medical Leave Act (FMLA) to living donors during the donation and recovery period.

The Board approved modifications to Policy 3.6.2.1 (Allocation of Blood Type O Donors) stating that, with the exception of Status 1 patients, blood type O donors may only be allocated to blood type O patients, or B patients with a MELD or PELD score greater than or equal to 30.

The Board approved modifications to Policy 2.7 (Removal of Non-renal Organs) clarifying that the policy applies to non-renal organs from controlled donation after cardiac death (DCD) donors.

The Board will request that the establishment of a long-term registry of living donors be given top priority by the NIH, NIAID, and other components of the Department of Health and Human Services.

The Board approved the Region 6 Lung Sharing Agreement to broaden the local allocation for lungs to all of Region 6, with the exception of Hawaii.

The Board directed that previous modifications to Policies 3.2.3 (Match System Access) and 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients) approved by the Board of Directors on June 26-27, 2003, shall be effective for all kidney transplants regardless of the date the transplant is performed, and that the prior effective date of January 1, 2003, approved by the Board of Directors shall be rescinded.

The Board directed that committees, when making policy recommendations to the Board regarding organ allocation, shall include recommendations specifically addressing the performance goals set forth in the OPTN Final Rule including performance indicators to measure the achievement of performance goals and transplant center performance. The performance indicators shall include baseline data evaluating how the policy being addressed is meeting the performance goals, the estimated amount of improvement to be achieved by the proposed modification, and the assessment required by the OPTN Final Rule.

With the addition of a nomination from the floor of Mary Nachreiner as a General Public Representative, the Board adopted the amended slate of nominees for election of members to the Board of Directors, as recommended by the Nominating Committee.

The Board approved modifications of the OPTN By-Laws, Appendix B (Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership), Section II (Transplant Hospitals), Attachment I to incorporate the previously approved changes to OPTN/UNOS By-Laws, Appendix B (Criteria for Institutional Membership), Section III (Transplant Programs) regarding criteria to perform pancreatic islet transplantation.

The Board resolved to recommend when the Secretary of the Department of Health and Human Services considers the recommendations of the Advisory Committee on Transplantation

(ACOT), that prevention and health promotion issues be included in the ACOT's consensus recommendation #11.

The Board rescinded its resolution changing the name of the Patient Affairs Committee to the Candidate Donor Recipient Committee and the title of the Vice President of Patient and Donor Affairs to the Vice President of Candidate Donor Recipient Affairs and reaffirmed that the name of the committee remains the Patient Affairs Committee, and that the title of the Vice President of Patient and Donor Affairs remains unchanged.

The Board declined to change the name of the Patient Affairs Committee to the "Candidate and Recipient Affairs Committee."

The Board resolved to support the formation of a donor committee and will reconsider any appropriate committee name change at a later date.

The Board declined to endorse the operating principles of the LifeSharers organization.

The Board endorsed the Ethics Committee's involvement regarding the National Conference of Commissioners on Uniform State Laws and the Uniform Anatomical Gift Act (UAGA).

The Board approved modifications to new Policy 3.4.7 (Allocation of Organs During Regional/National Emergency Situations) to outline the steps to be taken in the event of regional or national emergencies that compromise telecommunication, transportation or the function of or access to the OPTN wait list or matching system.

The Board approved modifications to Policy 5.5.2 that rescinded certain modifications that were approved by the Board at its June 2003 meeting and originally scheduled for implementation on January 1, 2004, regarding the validity and feasibility of the R-factor rating listed in the pending policy.