

**EXECUTIVE SUMMARY
OF THE MINUTES**

OPTN/UNOS

BOARD OF DIRECTORS MEETING

June 24-25, 2004

Minneapolis, Minnesota

Dr. Wiesner called the meeting to order at 8:30 a.m. on June 24, 2004. A quorum was present, and 36 members of the Board of Directors were in attendance during the meeting.

The Board approved the 2005 OPTN operating budget.

The Board approved an increase in the OPTN patient registration fee from \$447 to \$459.

The Board approved the 2003 Audited Financial Statements for OPTN Operations and the related OMB Circular A-133 compliance audit, as performed by PriceWaterhouseCoopers, LLP for the Year Ended September 30, 2003.

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 UNOS Bylaws Appendix B Attachment 1 (Standards for Histocompatibility Testing) Standard H3.100, proposed new policies 3.5.17 (Prospective Crossmatching) (for kidney transplantation) and 3.8.8 (Prospective Crossmatching) (for pancreas transplantation), and proposed new Appendix D to Policy 3, that develop within the bylaws a laboratory standard regarding crossmatching, and also develop a clinical practice policy on crossmatch requirements.
2. The Board approved new Policy 3.7.17 (Crossmatching for Thoracic Organs) to provide that a transplant program and its histocompatibility laboratory must have a joint written policy that states when a crossmatch is necessary.
3. The Board approved modifications to Policies 3.5.5 (Payback Requirements) and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals) that would elevate the priority at the local level of organ distribution assigned to high scoring high panel reactive antibody (PRA) candidates and pediatric candidates who surpassed their transplant goals ahead of payback debts and credits.
4. The Board approved modifications to Policies 3.5.3.3 (Mandatory Sharing) and 3.5.5 (Payback Requirements) ("Exemption of Kidneys Recovered from Donation after Cardiac Death (DCD) Donors from Sharing Requirements for Zero Antigen Mismatched Kidneys or Payback) to exempt donation after cardiac death (DCD) donor kidneys from the requirements of the zero antigen mismatch kidney sharing policy, except at the local level of organ distribution, as well as kidney payback policy. OPOs would retain the

option to offer DCD donor kidneys for payback, but would not be required to do so under the policy.

5. The Board approved modifications to Policies 3.5.3.3 (Mandatory Sharing) and 3.5.5 (Payback Requirements) (“ECD Kidney Exemption from Payback Sharing Requirements”) to exempt expanded criteria donor (ECD) kidneys from the requirements of the kidney payback policy. OPOs would retain the option to offer expanded criteria donor kidneys for payback, but would not be required to do so under the policy.
6. The Board approved modifications to Policies 3.6 (Pediatric Donor Liver Allocation Algorithm & Allocation Sequence for Patients with PELD or MELD Scores Less than or Equal to 6 (All Donor Livers)), 3.6.4.2 (Pediatric Patients Status), 3.6.4.2.1 (Pediatric Patient Reassessment and Recertification Schedule), 3.6.4.3 (Pediatric Liver Transplant Candidates with Metabolic Diseases), and 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma) that would assign the MELD score to candidates aged 12-17.
7. The Board approved modifications to Policy 3.6.2.1 (Allocation of Blood Type O Donors) that would allow any remaining blood type compatible candidates to appear on the match run list for blood type O donors after the blood type O and B candidate list has been exhausted at the regional and national level.
8. The Board approved modifications to Policy 3.6.4.4.1 (Adult Patient Reassessment and Recertification Schedule) and 3.6.4.2.1 (Pediatric Patient Reassessment and Recertification Schedule) that would reassign patients whose laboratory values are uncertified to a MELD/PELD score of 6.
9. The Board approved draft goals for liver and intestinal organ allocation policy development, submitted in response to a request made by the Board in November 2003.
10. The Board approved new Policies 3.4.7 (Allocation of Organs During Regional/National Emergency Situations), 3.4.7.1 (Regional/National Transportation Disruption), and 3.4.7.2 (Regional/National Communications Disruption), and 3.4.7.3 (OPTN Operational Disruption) to define procedures in Regional/National emergency situations.
11. The Board approved modifications to Policy 7.4.1, to address notification of the recipient’s death or graft failure.
12. The Board approved modifications to Policy 7.6.2.1, to clarify further the time period for transplant centers to verify the refusal reason entered by the OPO.
13. The Board approved modifications to Policies 7.7 (Submission of Death Notification) and 7.8.1, which address data submission standards to clarify the definition of hospital referral data.
14. The Board approved a resolution stating that the MELD/PELD allocation system adequately addresses the issue of biologic disadvantage for candidates awaiting liver transplantation.
15. The Board approved a resolution to require that serum sodium must be collected each time the MELD/PELD score is updated in UNetsm.
16. The Board approved amendments to Policy 3.6.2 (Blood Type Similarity Stratification/Points) to modify the phrase “A₂-blood type” to “non-A₁ blood type” for consistency with donor subtyping reporting practices.
17. The Board approved modifications to UNetsm to no longer automatically relist patients removed from the liver waiting list for living donor transplantation, to reflect the decreased importance of liver waiting time under the MELD system.

18. The Board approved modifications to Policy 3.6.4.5 (Liver Candidates with Exceptional Cases) that would permit MELD/PELD score increases at 3 months for exceptions.
19. The Board approved two new transplant centers; four new programs in existing member centers; three new hospital based histocompatibility laboratories, and one that is independent, for membership.
20. The Board approved the renewal of public members for two-year terms.
21. The Board granted full approval to three programs that now fully meet the membership requirements.
22. The Board approved a pilot project to collect individual data elements on all eligible deaths from a defined number of volunteer OPOs in order to improve understanding of donor potential and subject to the availability of personnel and financial resources.
23. The Board approved two requests for heart waiting time adjustment.
24. The Board approved six requests for lung waiting time adjustment.
25. The Board approved modifications to Policy 6.4.3 (Ad Hoc Organ Exchange) that would eliminate elements of the policy language that are no longer necessary.
26. The Board endorsed the dissemination of "A Proposal to Increase Organ Donation" to state governments, the Secretary of Health and Human Services, and the Council of State Governments.
27. The Board approved modifications to the Living Donor Registration Form that will change the functional status to a Karnofsky score, add "history of cigarette use" to the general medical information section, and incorporate biliary complication section into the liver donor registration form.
28. The Board approved modifications to Policy 3.2.3 (Match System Access) that require OPOs to use the OPTN/UNOS match system for allocating all organs from deceased donors.
29. The Board approved modifications to the local voluntary alternative system for assigning priority in kidney allocation to 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 proposed modifications would rank intended candidates (IC), in situations where more than one IC appeared on a match run, in order of date of donation from the living donor
30. The Board approved a request from Midwest Transplant Network regarding allocation of A₂ and A₂B Kidneys to expand its alternative system to allow the allocation of A₂ and A₂B kidneys from ECD donors to ABO B and O recipients.
31. The Board approved a request from LifeLink Foundation to dissolve the current alternative local unit (ALU) in Florida and instead, allocate pancreata and kidney/pancreas combinations using the OPO as the local unit for organ distribution, then statewide, then regionally, and then nationally.
32. The Board approved a request from LifeGift Organ Donation Center to apply the Houston and Fort Worth Alternative Local Unit to its entire service area and specifically, to the transplant centers in Lubbock, Texas.
33. The Board approved modifications to the Region 7 sharing agreement that would provide that donors meeting certain criteria (considered ECD donors) would not be offered for payback.

The Board approved modifications to Policies 3.5.5.1 (Kidney/Non-Renal Organ Sharing) and 3.5.5.2 (Deferment of Voluntary Arrangements) to increase the ABO blood group payback debt threshold from four to six in terms of an OPO's ability to retain local kidneys or receive shared kidneys to be used in a simultaneous kidney-pancreas transplant.

The Board approved modifications to Policy 3.8.1.5 (Islet Allocation Protocol) to better address the need for applying medical judgment in pancreatic islet transplantation decisions and avoid islet wastage.

The Board approved modifications to Policy 3.8.1.6 (Mandatory Sharing of Zero Antigen Mismatched Pancreata) to eliminate requirements for sharing isolated pancreata for zero antigen mismatched patients except for highly sensitized candidates, defined as candidates with panel reactive antibody (PRA) levels of 80% or higher. The intent is to allow for increased simultaneous pancreas-kidney transplantation by not requiring sharing of zero antigen mismatched pancreata, except for highly sensitized candidates whose opportunities for an isolated pancreas offer are limited.

The Board approved modifications to Policy 3.6.2.1 (Allocation of Blood Type O Donors) that state, 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 3.6 (Adult Donor Liver Allocation) that will allocate livers to patients with MELD/PELD scores of 15 or higher at the local and regional level prior to those with MELD/PELD scores of less than 15.

The Board declined to approve modifications to Policies 3.6 (Adult Patient Status), 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)) and 3.6.4.5 (Liver Candidates with Exceptional Cases) that would institute a minimum listing criteria of a MELD score of 10 for adult liver candidates. However, due to the potential negative effects of this rejected proposal on the pediatric population, the Board voted to expedite policy development regarding the sharing of pediatric donor livers with pediatric liver transplant candidates to include the policy development, public comment, and system programming processes.

The Board declined to approve modifications to the Region 5 liver sharing agreement for Status 1 candidates that would have *inter alia* eliminated paybacks. This proposal was reconsidered later in the meeting. Instead, the Board approved to submit for public comment proposed modifications to the Region 5 sharing agreement that would provide that paybacks will continue under the current Region 5 sharing agreement; and further provide a revised definition of Status 1; the payback of existing debts until zeroed out; retrospective review of all Status 1 listings; and Board review of the sharing agreement at 6 months and 1 year post implementation.

The Board approved modifications to Policy 6.4 (Exportation and Importation of Organs – Developmental Status) that would aid in verifying the legitimacy of organ offers from outside the U.S. and expanded the scope of the modifications to include donation after cardiac death (DCD) donor organs.

The Board approved proposed Living Liver Donor Evaluation Guidelines for potential living liver transplant recipient and donor evaluation including provisions for an independent donor team, psychiatric and social screening, and appropriate medical, radiological, and anesthesia evaluation.

The Board approved the proposed Living Kidney Donor Evaluation Guidelines for potential living liver transplant recipient and donor evaluation including provisions for an independent donor team, psychiatric and social screening, and appropriate medical, radiological, and anesthesia evaluation.

The Board endorsed the white paper, *Living Non-directed Organ Donation*, as an educational document, with minor modifications to maintain consistency with the National Organ Transplantation Act (NOTA).

The Board formally acknowledged public solicitation of organs for donation as an emerging phenomenon and created an ad hoc committee to explore and formulate standards of conduct regarding public solicitation of organs for donation.

The Board resolved to philosophically oppose the program being marketed by matchingdonors.com as it exploits vulnerable populations and undermines public trust in the equitable allocation of organs for transplantation.

The Board resolved to work toward developing a national living non-directed donation system.

The Board approved modifications to Policy 3.1.4 (Patient Waiting List), to ensure the accuracy of a transplant candidate's ABO type on the waiting list by requiring transplant centers to enter and maintain transplant candidate data electronically using UNetsm; requiring transplant candidate ABO typing on two separate occasions prior to listing; and listing transplant candidates with their actual ABO type.

The Board approved modifications to Policy 3.2.3 (Match System Access), requiring that two separate determinations of the donor's ABO type be performed prior to initiating the organ recovery incision, and providing more specific policy language for the process of distributing organs using the match system.

The Board approved specific new policy language for Policies 3.2.2.2 (UNetsm Indication of Multiple Listing), 3.2.2.3 (UNetsm Notification of Transplantation or Death of Multiple Listed Patients), 3.2.2.4 (Non-acceptance of Multiple Listing and/or Transferal of Primary Waiting Time), and 3.2.3 (Waiting Time Transferal and Multiple Listing), to effect several broadly worded resolutions regarding patient education, multiple listing and transferal of waiting time approved by the Board at its November 2003 meeting.

The Board approved new Policy 3.2.1.9 (Waiting Time Transferal) and modifications to Policy 3.2.2 (Multiple Listings Permitted) that will permit patients who desire to change transplant centers to move their accrued waiting time to a new transplant center.

The Board directed that the UNOS Communications Department develop certain patient education materials in response to the November 2003 Board directive requiring that every transplant program inform every patient about the options of multiple listing, transferring primary waiting time, transferring care to another transplant center without loss of accrued waiting time, and expanded criteria donor (ECD) kidney acceptance.

The Board approved modifications to Bylaws, Appendix B, Section III(C)(Transplant Programs), Section (15)(Social Support), to delineate specific elements of mental health and social support that should be provided to transplant candidates and recipients in a culturally competent manner.

The Board approved a new section of the Bylaws at Appendix B, Section III(C)(Transplant Programs), Section (20)(Clinical Transplant Pharmacist), that describes the responsibilities of a culturally competent clinical transplant pharmacist.

The Board resolved to submit for public comment a proposal that the Karnofsky Index replace the current method of collecting functional status on the current data collection forms.

The Board resolved to support a pilot study for the collection of SF 36 data for kidney, pancreas, heart, lung, and liver patients and recipients, and directed the appropriate committees to submit a detailed proposal for the pilot study to HRSA not later than September 30, 2004.

The Board approved the Missouri Statewide Alternative Local Unit for the allocation of livers. Under this ALU, after Status 1 candidates in Region 8, livers would go first to candidates on the recovering OPO's list, then to candidates on the other OPO's list that services Missouri, prior to allocation outside the state but within the Region.

The Board approved modifications to Bylaws Appendix B, Section IV, Part A (Live Donor Transplant Programs) to delineate the requirements for a live donor kidney transplant center.

The Board directed that post transplant tumor data continue to be collected, and that the OPTN/UNOS should take steps to facilitate complete and accurate collection of these data.

The Board approved an amendment to the Bylaws, Article VI, Section 6.1 (Permanent Standing Committees), to change the status of the Ad Hoc Transplant Coordinators Committee to that of a permanent standing OPTN/UNOS Committee.

The Board approved an analytic checklist that provides guidance to OPTN/UNOS committees when employing analytic modeling as a basis for policy development.

The Board approved as annual goals for the OPTN the following activities: develop and implement the OPTN Evaluation Plan; improve the mechanisms that seek guidance from the

transplant community and the general public with regard to appropriate future directions for OPTN policies and processes; develop organ-specific allocation policy performance goals and metrics; and improve and utilize innovative information technology for organ placement and for accurate, timely, and effective communication

The Board directed that, in developing policy recommendations regarding organ allocation, committees shall use the performance goals and metrics recently developed, endorsed by the Board, and referenced above as guidance in future policy development, revising such goals and metrics as necessary to keep them consistent with the vision of each committee. In each future allocation policy proposed for Board consideration, the Committee shall document how the proposal furthers the stated policy goals and what metrics will be used to monitor whether the policy may be furthering those goals.

The Board directed that the Executive Committee coordinate a retreat to begin, in concert with the Kidney/Pancreas Transplantation Committee, considering the concept of “net benefit” in kidney allocation policy.

The Board endorsed Wisconsin State Representative Steve Wieckert’s initiative to provide tax deductions for living organ donors.

The Board approved the Executive Committee actions with respect to implementing the OPTN Charter and Bylaws.

The Board formally adopted all UNOS Policies and interpretations thereof as in effect on April 30, 2004, as OPTN policies and criteria.

The Board endorsed two letters to Centers for Medicare and Medicaid Services (CMS) regarding reimbursement of pancreatic islet costs and diagnosis and procedure codes for pancreatic islet transplantation issues: one letter from the AOPO, ASTS and AST responding to a request for comments on a proposal published by CMS regarding Medicare payment for islet cell transplants and a second letter from the OPTN/UNOS that focuses on two issues found in the CMS proposal.

The Board approved modifications to Policies 3.7.6 (Status of Patients Awaiting Lung Transplantation), 3.7.9 (Time Waiting for Thoracic Organ Candidates), 3.7.9.2 (Waiting Time Accrual for Lung Candidates with Idiopathic Pulmonary Fibrosis (IPF)), and 3.7.11 (Allocation of Lungs), which substantially modify the lung allocation system. The revised allocation system will assign priority for donor lungs based on each candidate’s risk of death if the candidate does not receive a transplant, and on each candidate’s transplant benefit. Each candidate will receive a Lung Allocation Score on a 0-100 point scale and will be prioritized for lung offers by this score in descending order. The original proposal was modified to provide instead that the Thoracic Organ Transplantation Committee will propose changes to the tables of factors that predict risk of death on the waitlist and post transplant survival that must first be approved by the Board.

Requests for alternative distribution systems from LifeCenter NorthWest (WALC) and Organ Donor Center of Hawaii (HIOP) were withdrawn.

In a single vote, the Board approved two resolutions directing the Thoracic Organ Transplantation Committee to contact OPO's with lung and heart recovery and use data as part of a project to study data and recommend ways to improve both lung and heart recovery and use rates.

The Board directed the establishment of a voluntary, confidential system for members to report situations that could affect patient safety, organ availability, and organ utilization so that the prevalence of these situations can be monitored and reported, and recurrence can be prevented, with the goal of enhancing quality outcomes and systems.