

**EXECUTIVE SUMMARY
OF THE MINUTES**

OPTN/UNOS

BOARD OF DIRECTORS MEETING

June 26-27, 2003

Scottsdale, Arizona

Dr. Barker called the meeting to order at 8:30 a.m. on June 26, 2003. A quorum was present, and 33 of the Board members were in attendance during the meeting.

The Board approved the 2004 OPTN operating budget.

The Board approved the institution of a registration fee to be paid by the OPTN/UNOS member facility, for patients who received a living donor transplant but who were not previously on the Waiting List.

The Board approved an increase in the OPTN patient registration fee from \$415 to \$447.

The Board approved the 2002 Audited Financial Statements for OPTN Operations for the Year Ended September 30, 2002.

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 data elements on the current living donor data screens that are included on other electronic forms to ensure consistent formatting across the UNetsm system.
2. The Board approved modifications to the data elements in the UNetsm Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), and Transplant Recipient Follow-up (TRF) data collection screens.
3. The Board approved modifications to the data elements in the UNetsm Cadaver Donor Registration (CDR) data collection screens.
4. The Board approved modifications to the data elements in the UNetsm Donor Histocompatibility (DH) and Recipient Histocompatibility (RH) data collection screens.
5. The Board approved modifications to the data elements in the UNetsm Post Transplant Malignancies data collection screens.
6. The Board approved the addition of a series of contingency questions to the UNetsm Wait List Removal data collection screens to obtain more accurate documentation of patient deaths while on the Waiting List, during the transplant procedure, or after the transplant procedure.

7. The Board approved modifications to By-Laws Article VI – Permanent Standing Committees, to allow the Histocompatibility Committee vice chair to be elected by the histocompatibility laboratories.
8. The Board approved revisions to By-Laws Attachment 1-A – UNOS Test Data Criteria for New HLA Laboratories, to update the By-Laws with more current test data criteria.
9. The Board approved modifications to Policy 3.2.1.5 (Renal and Renal-Pancreas Combination Patient Listing) requiring that, to list a potential recipient of a kidney or a kidney-pancreas combination transplant on the UNOS System Waiting List, the potential recipient's complete HLA antigen information, at least 1 A, 1 B, and 1 DR antigens, must be entered into UNetsm.
10. The Board approved new Policy 9.11 (Release of HLA Type of a Patient's Prior Donor) to allow the release of patients' prior donors' HLA type to laboratories and/or transplant centers.
11. The Board approved new Policy 9.12 (Release of HLA Type of Donors and Recipients with Laboratory Name and Identifier) to allow the release of HLA typing results with laboratory identifier for resolving typing discrepancies.
12. The Board approved modifications to Policies 3.5.11.1 (The Point System for Standard Donor Kidney Allocation –Time of Waiting), 3.5.12.1 (The Point System for Expanded Criteria Donor Kidney Allocation – Time of Waiting), and 3.8 (Pancreas Allocation), to prospectively allow waiting time to accrue for an isolated cadaveric kidney transplant candidate or a combined kidney/pancreas transplant candidate registered on the Waiting List as being inactive, even if inactive beyond 30 days.
13. The Board approved applying the modifications to Policies 3.5.11.1 (The Point System for Standard Donor Kidney Allocation –Time of Waiting), 3.5.12.1 (The Point System for Expanded Criteria Donor Kidney Allocation – Time of Waiting), and 3.8 (Pancreas Allocation) to OPOs operating with OPTN/UNOS approved alternative systems for allocating kidneys and/or pancreata as well as the national system of kidney and pancreas allocation.
14. The Board approved modifications to Policy 3.5.3.3 (Mandatory Sharing), to assign priority for pediatric candidates with panel reactive antibody (PRA) <80% in the allocation of zero antigen mismatched kidneys before sensitized adult candidates with 21-79% PRA, but after sensitized candidates with 80% or higher PRA to ensure that pediatric candidates have an equitable opportunity to receive a zero antigen mismatched kidney.
15. The Board approved modifications to Policy 3.2.1.8 (Waiting Time Modification), to allow the OPTN/UNOS Kidney and Pancreas Transplantation Committee's actions with respect to kidney and pancreas waiting time modification requests to be final.
16. The Board approved modifications to Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)) relating to a reduction in the priority assigned to patients with Stage T1 and Stage T2 HCC. The modifications relate to policy changes for: extensions for patients with no evidence of tumor but and alpha-fetoprotein level of at least 500 ng/ml; extensions for patients whose tumors have been resected or ablated; and the submission of post-transplant pathology reports to the Regional Review Board (RRB).
17. The Board approved amendments to Policy 3.11.2 (Justification Form) to require on-line submission of Status 1 Justification forms for intestine transplant candidates.

18. The Board approved modifications to the By-Laws, Appendix B, Section C (8) (Survival Rates), to change the methodology used to identify poor performing programs.
19. The Board approved revisions to Policies 5.0 (Standard Packaging of Human Organs and Tissue Typing Material), 5.1 (Specimen Collection and Storage), 5.2 (Labeling), 5.3 (Documentation), 5.4 (Packaging), 5.5 (Standard Organ Package Specifications), and 5.6 (Standard Package Label Specifications) to improve organ procurement standards; facilitate OPTN member compliance by updating policies to reflect current accepted practices; and provide measurable outcomes.
20. The Board approved the recommendation that the minimum acceptable donor weight for heart allocation will be limited to 30% below the listing weight of the candidate and the maximum acceptable donor weight for heart allocation be limited to 100% above the listed weight of the candidate.
21. The Board approved the recommendation that the minimum acceptable donor height for lung allocation be limited to 8 inches below the listing height of the candidate, and the maximum acceptable donor height for lung allocation be limited to 12 inches above the listed height of the candidate.
22. The Board approved revisions to By-Laws, Appendix B – Standards for Histocompatibility Testing, to provide consistency with current laboratory practice.
23. The Board approved revisions to Appendix A to Policy 3 - HLA Antigen Values and Split Equivalences Table.
24. The Board approved the recommendation to delete By-Laws, Attachment 1-B, Submission of Proficiency Testing Data because UNOS has granted deemed status to ASHI to perform accreditation since UNOS is not an accrediting organization.
25. The Board approved revisions to Policy 3.5.14 (Broad and Split Antigen Specificities) to include matching for DR antigens.
26. The Board approved nine requests for waiting time modification and tentatively approved 13 additional requests for waiting time modification pending receipt of additional documentation, as recommended by the Kidney and Pancreas Transplantation Committee.
27. The Board approved a resolution stating that the additional Child-Turcotte-Pugh (CTP) data elements, not included in the MELD score (ascites, encephalopathy, albumen), will be collected indefinitely to allow continued research relating to improving the liver allocation system.
28. The Board approved the recommendation that UNOS and the American Society of Anesthesiologists create a forum to address the general shortage of anesthesia personnel and the potential shortage in quality anesthesia care for liver transplantation.
29. The Board approved new transplant centers and programs, as well as changes in program status, and renewal of public members.
30. The Board removed from OPTN/UNOS membership two inactive OPOs that do not have the required designation by the Secretary of HHS under § 1138(b) of the Social Security Act, and therefore do not qualify for membership as OPOs in the OPTN.
31. The Board approved a change of voting status from non-voting to voting for two tissue typing laboratories and one OPO.
32. The Board removed a tissue typing laboratory from the OPTN/UNOS membership since it does not meet current criteria for providing service to member transplant centers.

33. The Board removed an inactive liver transplant program from OPTN/UNOS membership because it does not meet the criteria for continued approval.
34. The Board approved modifications to Policy 7.0 (Data Submission Requirements), which address submission of hospital-specific referral information by OPOs.
35. The Board directed that the following transplantation-related terms be used, to the extent practicable: the term “deceased” donor instead of “cadaveric” donor; the term “candidate” be used in reference to a patient who is “pre-transplant;” and the term “recipient” be used in reference to a patient who is “post-transplant.”
36. The Board approved, for the purpose of testing the proposed modified on-line heart justification and variable forms, the implementation of such modified forms on the UNOS System as the heart Status 1A Exception listing form thus replacing the prior form used for listing Status 1A Exception patients.
37. The Board approved three requests for waiting time modification as recommended by the Thoracic Organ Transplantation Committee.
38. The Board approved modifications to Tennessee Transplant Society’s alternative system for kidney allocation to assign 1 point for each full year of waiting time.
39. The Board approved modifications to Region 1’s alternative system for kidney allocation to assign waiting time points and population distance points in the allocation of expanded criteria donor (ECD) kidneys just as Region 1 assigns waiting time points and population distance points in the allocation of standard criteria donor kidneys.
40. The Board approved the request for exemption from the November 14-15, 2002, Board-approved modifications to OPTN/UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) for California Transplant Donor Network for a period of three years, at which time, the OPO’s Alternative System will be re-evaluated.
41. The Board approved the request for exemption from the November 14-15, 2002, Board-approved modifications to OPTN/UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) for Gift of Hope Organ and Tissue Donor Network on a temporary basis pending completion of studies underway by the OPO and assessment of these studies by the OPTN/UNOS Kidney and Pancreas Transplantation Committee.
42. The Board approved the request for exemption from the November 14-15, 2002, Board-approved modifications to OPTN/UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) for Region 1 for a period of three years, at which time, the OPO’s Alternative System will be re-evaluated.
43. The Board approved the request for exemption from the November 14-15, 2002, Board-approved modifications to OPTN/UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) for Tennessee Transplant Services (TTS), for a two year period. After the expiration of two years, the TTS system will be re-evaluated.
44. The Board approved the request for exemption from the November 14-15, 2002, Board-approved modifications to OPTN/UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) for LifeGift Organ Donation Center (LifeGift), for a three year period, at which time, LifeGift’s Alternative System will be re-evaluated.
45. The Board approved requests for alternative allocation systems regarding original intended recipients from LifeNet, Center for Donation and Transplant and LifeGift Organ Donation Center.

46. The Board approved the extension of Pacific Northwest Transplant Bank's alternative system allowing ABO A₂ and A₂B donor kidneys to be transplanted into ABO B kidney recipients to expanded criteria donor (ECD) kidneys.
47. The Board approved modifications to the Region 8 Status 1 sharing agreement.
48. The Board approved the continuation of the Florida Statewide Alternative System for Hearts, Heart/Lungs, and Lungs.
49. The Board approved the continuation of the New York Statewide Alternative System for Hearts, Heart/Lungs, and Lungs.
50. The Board approved the continuation of the Tennessee Transplant Society Alternative System for Hearts, Heart/Lungs, and Lungs.
51. The Board approved a variance within Region 5 such that Status 1A Exception listings and extensions will remain subject to automatic referral to the RRB, and Statuses 1A(a) – (d) listings and extensions will be exempt from automatic referral to the RRB if the completed 1A(a) – (d) listing or extension applications for those patients demonstrate the necessary requirements to list those patients at those statuses.

The Board approved modifications to Policy 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients) to provide for reinstatement of waiting time for kidney recipients who experience (1) kidney graft removal within the first three months of transplant or (2) kidney graft failure within the first three months of transplant followed by non-function of the organ at three months from transplant evidenced by maintenance of the patient on dialysis or creatinine clearance level/GFR \leq 20 ml/min at three months from transplant. The criteria for time reinstatement under this revised policy shall apply to kidney transplants performed on and after January 1, 2003.

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

The Board approved modifications to Policies 3.6 (Allocation of Livers) and 3.11 (Intestinal Organ Allocation) to state that, regarding liver-intestine allocation, the liver may be allocated based upon priority for receipt of an intestine unless there is a Status 1 Liver patient in the Region.

The Board approved new Policy 3.6.4.7 (Combined Liver-Intestinal Candidates), which states that patients awaiting a combined liver-intestine transplant who are registered on both waiting lists will automatically receive an increase in their MELD/PELD score equivalent to a 10% risk of 3-month mortality.

The Board approved amendments to Policy 3.6.4.2.1 (Pediatric Patient Recertification and Reassessment Schedule) such that patients with a PELD score of 25 or greater be recertified every 14 days rather than every week, and the time frame for the currency of the laboratory values would be extended from 48 to 72 hours.

In a single vote, the Board approved the following three resolutions regarding histocompatibility testing:

1. Modifications to By-Laws Appendix B – Attachment 1 (Standards for Histocompatibility Testing) for inconsistencies with providing optimal patient care and histocompatibility requirements for appropriateness to organ transplantation and develop potential modifications in consideration of present clinical practices.
2. Approval of the position that UNOS does not support mandatory routine HLA typing or crossmatching for liver transplantation, and that this requirement is inappropriate for liver transplantation. Therefore, the Federal Regulations requiring HLA typing or crossmatching for liver transplantation should be modified accordingly.
3. Modifications to By-Laws Appendix B, Attachment 1 §13.000 (Other Organ Transplantation) regarding histocompatibility testing to change the requirements as they apply to thoracic organ transplantation.

The Board approved the recommendation that the UNOS Voluntary Local Renal Allocation Variance Using Cross-reactive HLA Antigen Groups (CREGs) be considered completed, pending programming on the UNOS System; and that the CREG matching should continue to be examined as a possible component of a standard deceased donor kidney allocation algorithm.

The Board approved revisions to Policies 2.1 (Host OPO), 2.2 (Evaluations of Potential Donors), 2.4 (Obtaining Consent), 2.5 (Obtaining Permission for Visiting Organ Procurement Teams to Enter the O.R. and Surgically Remove Organs), 2.6 (Organ Procurement Quality), 2.7 (Expediting Organ Procurement and Placement), 2.8 (Removal on Non-Renal Organs), and 2.9 (Multicultural and Diversity Issues). The proposed modifications are intended to improve organ procurement standards; facilitate OPTN member compliance by updating policies to reflect current accepted practices; and provide measurable outcomes.

The Board approved revisions to Policies 3.5.9 (Minimum Information/Tissue for Kidney Offer), 3.6.9 (Minimum Information for Liver Offers), 3.7 (Allocation of Thoracic Organs), and 3.8.5 (Minimum Information for Pancreas Offers) but specifically declined to approve revisions to Policy 3.3.1 (Donor Acceptance Criteria) as proposed by the OPO Committee. The proposed modifications are intended to improve organ procurement standards; facilitate OPTN member compliance by updating policies to reflect current accepted practices; and provide measurable outcomes.

The Board approved modifications to the By-Laws, Appendix B, III, C, that will describe the responsibilities and qualifications for clinical transplant coordinators, as proposed by the Membership and Professional Standards Committee.

The Board approved new Section IV (Standards for UNOS Certification of Live Kidney Donor Transplant Programs) as additions to By-Laws Appendix B (Criteria for Institutional Membership) including the requirement for the donor surgeon to have performed the requisite procedures in three years within a five-year period.

The Board approved new Section IV (Standards for UNOS Certification of Live Liver Donor Transplant Programs) as additions to By-Laws Appendix B (Criteria for Institutional Membership), including the requirement that the on site liver transplant surgeons have performed the requisite procedures in three years within a five-year period.

The Board directed that all programs desiring designation as an OPTN/UNOS-approved live donor transplant program must apply to the OPTN/UNOS Membership and Professional Standard Committee.

The Board approved modifications to the Living Donor Kidney and Liver Registration, Six-Week Follow-up, and 6-Month and 1-Year Follow-up forms.

The Board directed UNOS to develop the methodology for providing living donors with the information sent to the central registry on their behalf.

The Board directed UNOS to develop a standardized educational tool to be provided to all potential living donors and recipients.

The Board adopted a resolution recognizing the importance of collecting living donor follow-up data, and that the current plan proposed by the OPTN/UNOS Ad Hoc Living Donor Committee is reasonable to address the critical need for the information that donors need to make informed decisions.

The Board approved amendments to the data elements in the UNetsm Potential Transplant Recipient (PTR) data collection screens to optimize data reporting efficiency, accuracy, and utility and to consider how the PTR data collection process may be streamlined and yield more meaningful data.

The Board considered the Region 5 Status 1 Sharing Agreement and resolved that in the interest of the best care that patients can receive in Region 5, the Board of Directors supports the concept of using the MELD/PELD score to define when a payback can occur, and that a declined organ that is used for transplant can “wipe out” a payback. The Region 5 sharing agreement will be considered at the November 2003 Board of Directors meeting and any sharing agreement receiving less than 75% approval from the Region will be circulated for public comment.

The Board approved the implementation of updated MELD and PELD mortality risk curves in the liver allocation algorithm.

The Board recommended several measures involving the long term follow up of living donors including the transplant center’s responsibility for follow-up data submission for the first year after living donation, and the central registry/UNOS will collect follow-up data, either from the center or the donor, from years two through nine; the long-term follow-up of living donors undertaken by a central registry used to conduct research projects using sampled data; a unified registry approach; funding for the long-term follow-up registry; and informing donors prior to the surgery that data will be collected after donation.

The Board voted to support the development of universal legislation that will provide 30 days paid leave for state employees who donate organs for transplantation.

The Board directed that each potential living donor should have a psychosocial evaluation.

The Board approved modifications to Policy 3.7.12.3 (Essential Information for Lung Offers) and Policy 3.7.12.4 (Desirable Information for Lung Offers) to develop standardized guidelines for situations when bronchoscopies are required with lung offers and specifying that bronchoscopies should be arranged by the Host OPO or donor center.

The Board approved modifications to Policy 3.7.12.2 (Desirable Information for Heart Offers) to develop standardized guidelines for requesting a heart catheterization of a donor based upon the donor's medical history.

The Board approved the retrospective data collection of specific diagnostic variables at selected lung transplant centers on a selected cohort of waitlisted and transplanted lung patients for the purpose of collecting the data necessary for the ongoing refinement and improvement of the proposed lung distribution algorithm.

The Board endorsed the principle that the wishes of organ donors should be honored upon death to the extent medically feasible and encouraged the adoption and implementation in all states of the Uniform Anatomical Gift Act, as amended, pertaining to honoring the donor's wishes.

The Board approved the proposed Region 2 Status 1 Sharing Agreement, with the understanding that there are ongoing discussions regarding this proposal in the Region, and contingent upon 75% approval of the Regional members.

The Board inactivated a pancreas transplant program because it does not meet the requirements for continued approval as an active program.

The Board inactivated two functionally inactive kidney transplant programs that do not meet the requirements for "being active in the field of transplantation."

In a single vote, the Board approved the following seven resolutions, as recommended by the ABO Joint Subcommittee:

1. Modifications to Policy 3.1.4 (Patient Waiting List) to require transplant programs to have two separate verifications of transplant candidate ABO type. Candidates will not be active until the verification process is complete.
2. That transplant programs be required to enter candidate interactions into UNetsm beginning no later than January 1, 2004.
3. Modifications to Policy 3.2.3 (Match System Access) to require OPOs to have two separate verifications of the donor's ABO type and a process for ensuring the accuracy of the donor's ABO data on UNetsm.

4. Modifications to Policy 3.1.2 (Transplant Center) to establish that it is the responsibility of the transplanting surgeon at the transplant center receiving the organ offer for the surgeon's patient for ensuring medical suitability of donor organs for transplantation into the potential recipient, and to approve modifications to Policy 3.2.3 (Match System Access) requiring that organs must be allocated only to potential recipients identified on a match run.
5. Modifications to Policy 3.2.3 (Match System Access), which will modify policy to require that in instances in which an organ is accepted by a transplant center for a potential recipient, but is not utilized for that potential recipient, the organ be released to the Host OPO for appropriate re-allocation or assignment to the coordinating OPO for a local match run, effective pending review by the OPO Committee.
6. Modifications to Policy 5.0 (Standard Packaging of Human Organs and Tissue Typing Materials), requiring the OPO to perform two separate verifications of the data put on the labels and in the donor packet; requiring the Host OPO to package and label all organ containers and packaging materials; formalizing the Host OPO's documentation requirements; and formalizing the Host OPO's responsibility regarding the requirements of Policy 5.0, pending review and consideration by the OPO Committee.
7. Modifications to Policy 3.1.2 (Transplant Center) requiring transplant centers to perform and document verification of the donor's ABO type with organ package labels and with the potential's recipient ABO type before transplantation by two separate individuals.

During the discussion of the recommendations of the ABO Joint Subcommittee, the Board declined to approve recommended modifications to Policy 2.2.7 (Pertinent Tests) Subsection 2.2.7.1 (For All Potential Donors) that would have required that ABO typing be produced from two separate blood samples.

The Board declined to approve modifications to Policy 6.5 (Violations of Policies) as recommended by the Ad Hoc International Relations Committee however, the Board approved modifications to Policy 6.5 (Violations of Policies) such that persistent violations without justification or explanation, or failure to respond to inquiries will be reported to the Membership and Professional Standards Committee.

The Board approved modifications to Policies 7.0 (Data Submission Requirements), 7.1 (OPTN Reporting Requirements), 7.5 (Submission of Feedback Information), and 7.7 (Submission of Donor Referral Information) to improve the process by which transplants and deaths are identified and counted statistically.

The Board approved the proposed change of title of the "Vice-President of Patient and Donor Affairs" to "Vice-President of Candidate, Donor, and Recipient Affairs." This action will be reconsidered by the Board at its next meeting following the requisite notice for an amendment to the By-Laws.