

OPTN/UNOS Policy Oversight Committee
Report to the Board of Directors
June 21-22, 2010
Richmond, Virginia

Summary

I. Action Items For Board Consideration

- The Board is asked to approve modifications to Policy 3.4 (Organ Procurement, Distribution, and Alternative Systems for Distribution or Allocation). (Item 1, Page 3)

II. Other Significant Items

- The Committee submitted a proposal for public comment in March, 2010. The proposed modifications to the data elements on the Tiedi[®] forms *will not* be submitted to the Board of Directors at this time. (Item 2, Page 8)
- The Committee reviewed proposals circulated for public comment in November 2009 and March 2010. (Item 3, Page 8).

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Report to the Board of Directors
June 21-22, 2010
Richmond, Virginia

Edward R. Garrity, Jr., M.D., M.B.A., Chair

This report represents the deliberations of the Policy Oversight Committee during conference calls on January 8, January 28, February 15, and April 16, 2010.

Review of Committee-sponsored Public Comment Item, October 2009

1. Variance Appeals Proposal. The Committee submitted a proposal for public comment in October 2009 that is intended to improve the variance appeals process. The proposed modifications describe how an OPTN member may appeal a variance decision, and the role of the relevant committees and Policy Oversight Committee (POC) in the appeals process.

A detailed description of this proposal is provided in **Exhibit A**. The Resource Assessment and Impact Statement for this proposal can be found in **Exhibit B**.

During the February 15, 2010, conference call, the Committee reviewed the public, committee, and regional comments that were received on this proposal. All 7 committees that reviewed the proposal were in support (Kidney Transplantation Committee, Minority Affairs Committee, OPO Committee, Pancreas Transplantation Committee, Pediatric Transplantation Committee, Thoracic Organ Transplantation Committee, and Transplant Administrators Committee), as well as all 11 regions, the American Society of Transplant Surgeons, and the American Society of Transplantation.

As of the public comment deadline on February 5, 2010, UNOS had received 38 responses regarding this policy proposal. Of these, 36 (94.74%) supported the proposal, 2 (5.26%) opposed the proposal, and 0 (0%) had no opinion. Of the 38 who responded with an opinion, 36 (94.74%) supported the proposal and 2 (5.26%) opposed the proposal. The Committee responded to each of the comments and the responses can be found in **Exhibit A**.

The Committee submits the following for consideration by the Board of Directors:

**** RESOLVED, that Policy 3.4 (Organ Procurement, Distribution and Alternative Systems for Organ Distribution or Allocation) shall be amended as set forth below, effective following notice to the membership.**

- 3.4 **ORGAN PROCUREMENT, DISTRIBUTION AND ALTERNATIVE SYSTEMS FOR ORGAN DISTRIBUTION OR ALLOCATION.** The following policies apply to organ procurement, distribution and alternative systems for organ distribution or allocation.

[There are no changes to Policies 3.4.1 through 3.4.6 and where indicated]

- 3.4.7 **Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems.** The following policies define the

processes for applying for a new or modified AAD System, review of such systems and withdrawal from such systems by any one or more of the participants.

3.4.7.1 Application. *(No changes)*

3.4.7.2 Data Submission Requirements. *(No changes)*

3.4.7.3 Dissolution of Alternative Assignment Systems. *(No changes)*

3.4.7.4 Modifications of Alternative Point Assignment Systems, Sharing Arrangements and ALUs. *(No changes)*

3.4.7.5 AAD Systems Approved Prior to March 15, 2005. *(No changes)*

3.4.7.6 Appealing A Decision on An Alternative Organ Distribution or Allocation System. A participating Member can appeal a committee's or a Board of Directors' decision on an alternative organ distribution or allocation system. To appeal a decision on an alternative organ distribution or allocation system, the participating Member must follow the process described below.

a. Appealing A Committee's Decision

The committee will notify the participating Member in writing of its decision within 10 business days, inclusive, of the meeting in which it determined the outcome of the alternative organ distribution or allocation system.

To express its intent to appeal a committee's decision on an alternative organ distribution or allocation system, the participating Member must do so in writing and within 30 days, inclusive, of the committee's communication of its decision. The participating Member must appeal a committee's decision *before* the Policy Oversight Committee (POC) reviews this recommendation. The participating member should contact the OPTN Contractor for the POC meeting schedule.

In considering the appeal, the committee will *only review evidence not considered previously*. The committee will evaluate the appeal as it would the application (see Policy 3.4.7.1 – Application). The participating Member may choose to take part in this appeal discussion. The committee may request additional information from the participating Member. Once the committee makes its final decision on the alternative organ distribution or allocation system, the participating Member *cannot request another appeal* until the POC *and* the Board of Directors decide on the alternative organ distribution or allocation system.

In its evaluation of the alternative organ distribution or allocation system, the POC may request additional information from the

committee, who will communicate this query to the participating Member. The committee will submit any information received from the participating Member to the POC. The POC will then decide on the alternative organ distribution or allocation system and submit its recommendation to the Board of Directors. The Board of Directors will consider the alternative organ distribution or allocation system, including the decisions of the committee and POC. The participating Member may choose to take part in this meeting of the Board of Directors.

If the Board of Directors decides in favor of the alternative organ distribution or allocation system, then the alternative organ distribution or allocation system is approved for the trial period requested by the participating Member. If the Board of Directors decides against the alternative organ distribution or allocation system, then the alternative organ distribution or allocation system is not approved.

b. Appealing a Board of Directors' Decision

To appeal the decision of the Board of Directors on an alternative organ distribution or allocation system, the participating Member of the alternative organ distribution or allocation system may appeal directly to the Secretary of the Health and Human Services (HHS), in accordance with the OPTN Final Rule, 42 CFR § 121.4 (OPTN policies: Secretarial review and appeals).

3.4.8 Application, Review, Dissolution and Modification Processes for Variances.

The following policies define the processes for applying for a new or modified Variance, review of such systems by, and withdrawal from such systems by any one or more participants.

3.4.8.1 Application. *(No changes)*

3.4.8.2 Data Requirements. *(No changes)*

3.4.8.3 Appealing A Variance Decision. to Secretary. The participating Member can appeal a committee's or Board of Directors' decision on a variance. To appeal a decision on a variance, the participating Member must follow the process described below.

a. Appealing a Committee's Decision

The committee will notify the participating Member in writing of its decision within 10 business days, inclusive, of the meeting in which it determined the outcome of the variance.

To express its intent to appeal, the participating Member must do so in writing and within 30 days, inclusive, of the committee's communication of its decision. The participating Member must appeal a committee's decision *before* the Policy Oversight

Committee (POC) reviews this recommendation. The participating member should contact the OPTN Contractor for the POC meeting schedule.

In considering the appeal, the committee will *only review evidence not considered previously*. The committee will evaluate the appeal as it would a variance application (see Policy 3.4.8.1 – Application). The participating Member may choose to take part in this appeal discussion. The committee may request additional information from the participating Member. Once the committee makes its final decision on the variance, the participating Member *cannot request another appeal* until the POC and the Board of Directors decide on the variance.

In its evaluation of the variance, the POC may request additional information from the committee, who will communicate this query to the participating Member. The committee will submit any information received from the participating Member to the POC. The POC will then decide on the variance and submit its recommendation to the Board of Directors. The Board of Directors will consider the variance, including the decisions of the committee and POC. The participating Member may choose to take part in this meeting of the Board of Directors.

If the Board of Directors decides in favor of the variance, then the variance is approved for the trial period requested by the participant. If the Board of Directors decides against the variance, then the variance is not approved.

b. Appealing a Board of Directors' Decision

To appeal the decision of the Board of Directors, the variance applicant may appeal directly to the Secretary of the Health and Human Services (HHS), in accordance with the OPTN Final Rule, 42 CFR § 121.4 (OPTN policies: Secretarial review and appeals).

3.4.8.4 Termination of Member Participation in Variance. *(No changes)*

3.4.8.5 Modification of Variance. *(No changes)*

3.4.9 Development, Application, Review, Dissolution and Modification Processes for Committee-Sponsored Alternative Systems. The following policies define the processes for developing a new or modified Committee-Sponsored Alternative System, application to participate in such systems, review of such systems, and withdrawal from such systems by any one or more participants.

3.4.9.1 Development and Application. *(No changes)*

3.4.9.2 Data Requirements. *(No changes)*

3.4.9.3 Termination of Member Participation in Committee-Sponsored Alternative System. *(no changes)*

3.4.9.4 Modification of Committee-Sponsored Alternative System. *(no changes)*

3.4.9.5 Committee-Sponsored Alternative Systems Approved Prior to March 15, 2005. *(no changes)*

3.4.9.6 Appealing A Decision on A Committee-Sponsored Alternative System.

The committee sponsoring a Committee-Sponsored Alternative System may appeal the decision of the Policy Oversight Committee (POC), but cannot appeal a decision of the Board of Directors.

a. Appealing the POC's Decision

The POC will notify the sponsoring committee in writing of its decision within 10 business days, inclusive, of the meeting in which it determined the outcome of the variance.

To express its intent to appeal, the sponsoring committee must do so in writing and within 30 days, inclusive, of the POC's communication of its decision. The sponsoring committee must appeal the POC's decision *before* the Board of Directors reviews the POC's recommendation.

In considering the appeal, the POC will *only review evidence not considered previously*. The POC will evaluate the appeal as it would an application for a Committee-Sponsored Alternative System (see Policy 3.4.9.1 – Development and Application). The sponsoring committee may choose to take part in this appeal discussion. The POC may request additional information from the sponsoring committee. Once the POC makes its final decision on the variance, the sponsoring committee *cannot request another appeal* until the Board of Directors decide on the Committee-Sponsored Alternative System.

In its evaluation of the Committee-Sponsored Alternative System, the POC may request additional information from the sponsoring committee. Once the sponsoring committee submits any information requested by the POC, the POC will then decide on the Committee-Sponsored Alternative System and submit its recommendation to the Board of Directors. The Board of Directors will consider the Committee-Sponsored Alternative System. The sponsoring committee may choose to take part in this meeting of the Board of Directors.

If the Board of Directors decides in favor of the Committee-Sponsored Alternative System, then the Committee-Sponsored Alternative System is approved for the trial period requested by the committee. If the Board of Directors decides against the Committee-Sponsored Alternative System, then the Committee-Sponsored Alternative System is not approved.

b. Appealing the Board of Directors' Decision

Only a member participating in an existing Committee-Sponsored Alternative System can appeal the Board of Directors' decision on a Committee-Sponsored Alternative System.

To appeal the decision of the Board of Directors on a Committee-Sponsored Alternative System, the member participating in an approved Committee-Sponsored Alternative System may appeal directly to the Secretary of the Health and Human Services (HHS), in accordance with the OPTN Final Rule, 42 CFR § 121.4 (OPTN policies: Secretarial review and appeals).

[There are no further changes to Policy 3.4.]

2. Office of Management and Budget (OMB) Forms Review. All OPTN forms must be reviewed and approved by the OMB every three years. The OPTN initiated a review of the data elements in early 2009 in order to identify any necessary changes. Following a comprehensive review of all the data elements by OPTN Committees, the Ad Hoc Data Management Group (AHDMG), an Expert Panel on Cardiovascular Risk Factors in Renal Candidates/Recipients (Expert Panel), and the POC, the Committee submitted a proposal for public comment in March 2010. The purpose of the proposed changes was to add important variables that are not currently collected, clarify or modify questions on the forms, and eliminate variables that are redundant or no longer needed.

A detailed description of this proposal, including copies of all comments received, is provided in **Exhibit C**.

As of the public comment deadline of April 16, 2010, 67 responses have been submitted to UNOS regarding this policy proposal. Of these, 27 (40.30%) supported the proposal, 34 (50.75%) opposed the proposal, and 6 (8.96%) had no opinion. Of the 61 who responded with an opinion, 27 (44.26%) supported the proposal and 34 (55.74%) opposed the proposal. A majority of the OPTN Committees that reviewed the proposal were in support, with the Kidney Transplantation Committee, Ad Hoc Disease Transmission Advisory Committee, and Thoracic Organ Transplantation Committee providing significant suggestions and comments. The Transplant Administrators Committee *did not* support the proposal. The American Society of Transplant Surgeons and the American Society of Transplantation *did not* support the proposal.

Due to the significant opposition to this proposal, OPTN/UNOS leadership decided that the current proposal **would not** be submitted to the Board of Directors in June 2010.

Review of Proposals Circulated for Public Comment, November 2009 (Scores Provided in Table 1)

3. Proposal to Add a Valuable Consideration Disclosure to the Bylaws (Living Donor Committee). Under this proposal, transplant centers would be required to document that potential living organ

donors have been informed that the sale or purchase of human organs (kidney, liver, heart, lung, pancreas and any other human organ) is a federal crime.

The Committee did have some concerns about not having a similar requirement for recipients. It was noted by UNOS staff that this issue is being addressed in two phases, with additional work and analyses being done to address the recipients.

The Committee used the scorecard to assess this policy, and the proposal received an overall score of 12. The proposal received an average score of greater than 3.0 in the following category: Patient safety and transplant oversight.

The Committee supported this proposal by a vote of 7 for, 0 against, and 0 abstentions.

Review of Proposals Circulated for Public Comment, March 2010 (Scores Provided in Table 1)

4. Proposed Ohio Alternative Local Unit (ALU) (Liver and Intestinal Organ Transplantation Committee)

Three Donation Service Areas (LifeBanc, Life Connection of Ohio and LifeCenter Organ Donor Network) are requesting a single, combined new Alternative Local Unit in the State of Ohio. There will be a single waiting list within the ALU for liver allocation. This will allow for better and more efficient allocation of organs to those on the waiting list with the most urgent need over a larger geographic area.

The Committee supported this proposal because it does represent broader sharing and was supported by the Liver and Intestinal Organ Transplantation Committee. It was noted that while there is a push to limit variances, certain agreements do provide a benefit to transplant candidates.

The Committee used the scorecard to assess this policy, and the proposal received an overall score of 9.4. The proposal received average score of 1.8 or greater in the following categories: best use of donated organs and operational effectiveness.

The Committee unanimously supported this proposal by a vote of 6 for, 0 against, and 0 abstentions.

5. Proposed OneLegacy Variance for Segmental Liver Transplantation (Liver and Intestinal Organ Transplantation Committee)

OneLegacy and the five liver transplant programs in its donation service area (DSA) are proposing a variance to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation). This variance would permit the institutions performing the right and left lobe splits to transplant one lobe into the institution's index patient and the other lobe into any other medically suitable patient listed at the institution. The variance is intended to increase the donor pool by providing an incentive to the institution receiving a liver offer to split a good-quality organ and transplant it in two recipients (an adult and a child) rather than transplanting the entire organ in one recipient.

The Committee agreed that it would have been advantageous to have the two split liver variances set up the same way so the Liver and Intestinal Organ Transplantation Committee could evaluate how the variance works in two different regions.

The Committee used the scorecard to assess this policy, and the proposal received an overall score of 10.4. The proposal received average score of greater than 1.8 in the following categories: Statement of problem and assessment.

The Committee supported this proposal by a vote of 5 for, 1 against, and 0 abstentions.

6. Proposed Region 2 Variance for Segmental Liver Transplantation (Liver and Intestinal Organ Transplantation Committee)

Region 2 is proposing a variance to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation). This variance would allow a transplant center in Region 2 that accepts a liver for a candidate suitable for a segmental transplantation to transplant the right lobe into the institution's index patient and the left segment into any other medically suitable patient listed at that institution or an affiliated pediatric institution. This variance is intended to increase the number of transplants, allowing a single liver to be divided into two segments for transplantation, and thus removing two patients from the waiting list instead of one.

As mentioned previously, the Committee agreed that it would have been advantageous to have the two split liver variances set up the same way so the Liver and Intestinal Organ Transplantation Committee could evaluate how the variance works in two different regions.

The Committee used the scorecard to assess this policy, and the proposal received an overall score of 9.8. The proposal received a score of greater than 1.8 in the following category: Statement of problem.

The Committee supported this proposal by a vote of 5 for, 1 against, and 0 abstentions.

7. Proposal to Develop an Efficient, Uniform National Pancreas Allocation System: Affected Policies: Policy 3.8 (Pancreas Allocation Policy), Policy 3.5 (Kidney Allocation Policy), Policy 3.2 (Waiting List), Policy 3.3 (Acceptance Criteria), Policy 3.4 (Organ Procurement, Distribution And Alternative Systems For Organ Distribution Or Allocation), and Policy 3.9 (Allocation Systems for Organs not Specifically Addressed) (Pancreas Transplantation Committee)

The purpose of this proposal is to improve the national pancreas allocation system. This improvement is consistent with the following OPTN long-range strategic goals and priorities:

- to increase geographic equity in access and waiting time to deceased donor organs for transplantation;
- to maximize capacity of deceased donor organ transplantation; and
- to achieve operational efficiency and cost-effectiveness of implementing and maintaining the organ allocation system.

Specific objectives of the proposed allocation system for pancreas transplantation:

- reduce geographic inequities of pancreas utilization, access to transplantation, and transplant waiting time;
- maximize capacity by improving the opportunity for pancreas candidates to receive a transplant;
- enhance efficiency and cost-effectiveness, and minimize complexity of implementing and maintaining the operational requirements of a new pancreas allocation system; and

- optimize pancreas transplant access without adversely affecting kidney transplantation. Specifically, the Committee evaluated the transplant volume for adult and pediatric kidney recipients as well as ethnicity, age, and gender of recipients.

Methodology to achieve these objectives:

- combine pancreas-alone (PA) and simultaneous pancreas-kidney (SPK) candidates onto a single match run list;
- allow local candidates who are allocated a pancreas from the combined list but who also require a kidney transplant, to receive a kidney independently of the kidney-alone match run if they meet specific qualifying criteria;
- institute objective medical qualifying criteria relating to renal dysfunction and diabetes for SPK candidates to accrue waiting time;
- allocate deceased donor pancreata separately from the current kidney allocation system so that pancreas candidates are allocated organs that precede kidney paybacks and pediatric and adult kidney-alone (KI) recipients; and
- monitor allocation of standard criteria deceased donor kidneys for pediatric and adult KI recipients and SPK recipients with respect to donor ages ≤ 35 and > 35 years, as well as ethnicity, age and gender.

It was noted that from a logistical/programming perspective it would be advantageous to have a new pancreas allocation system in place before the kidney allocation system is modified.

The Committee used the scorecard to assess this policy, and the proposal received an overall score of 22.8. The proposal received average high scores in every category on the scorecard.

The Committee supported this proposal by a vote of 6 for, 0 against, and 1 abstention.

8. Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events: Affected/Proposed Policies: Policies 2.0 (Minimum Procurement Standards for An Organ Procurement Organization), 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Diseases or Medical Conditions, Including Malignancies, of Donor Origin), and 5.5 (Documentation Accompanying the Organ or Vessel) (Ad Hoc Disease Transmission Advisory Committee)

The proposed modifications are meant to clarify and/or improve current OPO and transplant center requirements for screening for, communicating and reporting all potential or confirmed donor-related disease and malignancy transmission events. These changes are expected to:

- Help improve patient safety and recipient outcomes by making policy consistent with current clinical testing practices in the organ recovery transplant communities and creating a Patient Safety Contact;
- Place all content related to donor evaluation and screening into one policy section;
- Further define and standardize the elements of informed consent and the communication of clinically significant information regarding potential disease transmission events; and

- Provide a clear, plain language policy format that will be easier for members and other readers to understand and follow.

The Committee used the scorecard to assess this policy, and the proposal received an overall score of 14. The proposal received average score of greater than 2.3 in the following categories: Patient safety and transplantation oversight and patient impact.

The Committee unanimously supported this proposal by a vote of 6 for, 0 against, and 0 abstentions.

9. Proposal to Update HLA Equivalences Tables Affected/Proposed Policy: UNOS Policy 3 Appendix A (Histocompatibility Committee)

The purpose of this proposal is to update the tables in Appendix 3A to reflect changes in HLA typing practice and to improve the utility of the unacceptable antigens. Appendix 3A includes 2 tables, one listing HLA antigen designations that should be considered equivalent for purposes of matching kidney candidates and donors for the HLA-A,-B, and -DR antigens (HLA Antigen Values and Split Equivalences) and a second for determining which donor HLA antigens are unacceptable based on the unacceptable HLA-antigens listed for a sensitized candidate (HLA A, B, C, DR, and DQ Unacceptable Antigen Equivalences).

The Committee used the scorecard to assess this bylaw change, and the proposal received an overall score of 16.5. The proposal received average score of greater than 2 in the following categories: Patient safety and transplantation oversight, patient impact, and degree of criticality.

The Committee supported the proposal by a vote of 6 for, 0 against, and 0 abstentions.

10. Proposal to Require that Deceased Donor HLA Typing be Performed by DNA Methods and Identify Additional Antigens for Kidney, Kidney-pancreas, Pancreas, and Pancreas Islet Offers Affected/Proposed Policy: UNOS Bylaws Appendix B Attachment IIA - Standards for Histocompatibility Testing D HLA Typing D1.000 Essential Information for Kidney Offers 3.8.2.2 Essential Information for Pancreas Offers (Histocompatibility Committee)

This proposal would require that OPOs and their associated laboratories perform HLA typing of deceased donors by DNA methods and identify the HLA-A, -B, -Cw, -DR and -DQ antigens before making any kidney, kidney-pancreas, pancreas, or pancreas islet offers.

The Committee used the scorecard to assess this policy change, and the proposal received an overall score of 17. The proposal received average score of greater than 2.0 in the following categories: Patient impact, best use of donated organs and patient safety and transplantation oversight.

The Committee supported the proposal by a vote of 6 for, 0 against, and 0 abstentions.

11. Proposal for the Placement of Non-Directed Living Donor Kidneys: Affected Policy: 12.5.6 (Recipient Selection for Organs from Nondirected Living Donor Organs) (Living Donor Committee)

This proposal would establish procedures for the placement of non-directed living donor kidneys. Under the proposal, transplant centers would select the recipient of non-directed living donor

kidneys based on a list generated by the OPTN computer system used to identify potential recipients for transplant. This list is referred to as a match run. The goal of this proposal is to foster equitable organ placement and safety of the recipient.

The Committee had concerns about where centers would maintain documentation on the criteria used to place a non-directed donor living kidney and how the documentation would be monitored. It was noted that there would not be a limitation on the placement of a non-directed living donor kidney, however the documentation must provide a rationale for any deviation from the match run. There was concern about creating extra paperwork for transplant centers when they are using sound medical judgment to place the organs. The Committee had concerns about the need for this requirement if it's not going to be monitored or regulated in any way. If sound medical judgment is used to place kidneys in the appropriate recipient, why do centers need to document what potential recipients did not receive the kidney. It was also noted that if an appropriate candidate is listed on a transplant center's match run, why would there be a need for an exception to the match run? Another question was raised about whether there is information available about the current practices and if there is a problem with the way it is currently being done. The Living Donor Committee representative noted that the reason for this proposal is to make sure there is transparency in the process. The intent is not to change how this practice is done, it is intended to provide more information about how the process works.

The Committee used the scorecard to assess this policy change, and the proposal received an overall score of 12.3. The proposal received average score of greater than 1.5 in the following categories: Patient impact, degree of criticality, maximum capacity, and statement of problem.

The Committee *did not* support the proposal by a vote of 1 for, 5 against, and 0 abstentions.

12. Proposal to Require Reporting of Non-utilized and Redirected Living Donor Organs - New Proposed Policy: Submission of Non-utilized Living Donor Organs (Policy 12.8.5) and Submission of Redirected Living Donor Organs (Policy 12.8.6) (Living Donor Committee)

These proposals require that the organ recovery center report all instances of:

- living donor organs recovered but not utilized for transplant; and
- living donor organs recovered but then redirected and transplanted into a recipient other than the intended recipient.

These events would be reported through the UNetSM Patient Safety System. If a living donor organ is transplanted into a recipient other than the intended recipient, all required donor and recipient information must still be submitted through Teidi.

The question was raised about who will monitor and oversee this information. Since this information will be entered into UNetSM, the OPTN will be able to run reports, and the plan is to have the MPSC monitor it. There is currently limited information about what is happening with these organs and the intent of this proposal is to help collect valuable information.

The Committee used the scorecard to assess this policy change, and the proposal received an overall score of 13. The proposal received the highest score (2.8) in the following category: Patient safety and transplantation oversight.

The Committee supported the proposal by a vote of 6 for, 0 against, and 0 abstentions.

13. Proposal to Require a Use of a Standardized, Internal Label that is Distributed by the OPTN and that Transplant Centers Notify the Recovering OPO when they Repackage an Organ
Affected/Proposed Policy: Policy 5.0 – Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials (Organ Procurement Organization (OPO) Committee)

Current OPTN policy only requires that the external label distributed by the OPTN contractor be used for transporting organs and vessels. This proposed policy change would require OPOs and transplant centers to also use standardized, internal labels that are distributed by the OPTN contractor for organ and vessel transport and for vessel storage. This change will make both internal and external labeling consistent throughout the U.S. The proposal also:

- requires transplant centers to notify the recovering OPO when they repackage an organ;
- makes the language consistent by changing the term “provided” by the OPTN contractor to the term “distributed” by the OPTN contractor;
- moves Policy 2.5.6.1 which lists the required documentation that accompanies an organ or vessel to policy 5.5.1; and
- clarifies labeling requirements for vessel storage

There was a question raised about the packaging requirements for organs. The Committee supported this proposal as long as there was clarification regarding the requirement for external and internal packaging. Following the meeting, UNOS staff confirmed that current policy language allows for the use of coolers and does not require the use of a rigid internal container for hearts, lungs, livers, and intestines.

The Committee used the scorecard to assess this policy change, and the proposal received an overall score of 16.3. The proposal received average score of greater than 2.0 in the following categories: Statement of problem and degree of criticality.

The Committee supported the proposal by a vote of 6 for, 0 against, and 0 abstentions.

Table 1	Valuable Consideration Disclosure	Proposed Ohio ALU	Proposed One Legacy Variance	Proposed Region 2 Variance
Patient Safety and Transplantation Oversight	3.0	0.4	-0.2	-0.2
Best Use of Donated Organs	0.0	1.8	1.6	1.2
Geographic Equity	0.0	1.2	0.2	0.6
Maximum Capacity	0.0	0.6	1.4	1.2
Operational Effectiveness	2.0	1.8	0.4	0.8
Statement of the problem	2.0	1.4	1.8	1.8
Evidence	2.0	0.8	1	0.8
Assessment	2.0	1.0	1.8	1.4
Patient Impact	0.0	0.2	1.4	1.2
Degree of Criticality	1.0	0.2	1	1
Total	12	9.4	10.4	9.8

Table 1 (continued)	Pancreas Allocation System	DTAC Proposal	HLA Equivalences Tables	Donor HLA typing
Patient Safety and Transplantation Oversight	1.8	2.8	2.0	2.8
Best Use of Donated Organs	3.0	1.3	1.5	2.5
Geographic Equity	2.5	1.3	1.5	1.0
Maximum Capacity	2.8	0.0	1.0	0.3
Operational Effectiveness	1.8	0.5	1.5	1.8
Statement of the problem	2.5	1.8	1.5	1.8
Evidence	2.3	1.3	1.8	1.5
Assessment	2.3	1.3	1.5	1.8
Patient Impact	2.0	2.3	2.0	2.0
Degree of Criticality	2.0	1.8	2.3	1.8
Total	22.8	14	16.5	17

Table 1 (continued)	Placement of Non-directed living donor kidneys	Reporting of non-utilized and redirected living donor organs.	Standardized labeling proposal
Patient Safety and Transplantation Oversight	1.3	2.8	2.8
Best Use of Donated Organs	1.3	1.3	1.8
Geographic Equity	0.8	0.8	0.8
Maximum Capacity	1.5	0.8	0.3
Operational Effectiveness	1.3	0.8	1.8
Statement of the problem	1.5	2	2.0
Evidence	0.5	0.3	1.8
Assessment	1.3	1.8	1.5
Patient Impact	1.5	1.3	1.8
Degree of Criticality	1.5	1.5	2.0
Total	12.3	13	16.3
Each of the 10 categories may receive from -3 to 3 points, with zero being neutral.			

Policy Oversight Committee		Jan. 8, 2010 Conference Call	Jan. 28, 2010 Conference Call	Feb. 15, 2010 Conference Call	April 16, 2010 Conference Call
Edward Garrity Jr., MD, MBA	Chair	X	X	X	X
John Freidewald, MD	At-Large	X		X	
David Axelrod, MD	At-Large	X	X		X
Lori Brigham, MBA	At-Large	X	X	X	
David Campbell, MD	At-Large	X	X	X	
Laura Ellsworth, MBA	At-Large	X	X	X	X
Silas Norman, MD	At-Large	X	X	X	X
Mary Kelleher, MS, CIP	At-Large	X	X	X	X
Kim Olthoff, MD	At-Large	X	X	X	X
Mark Barr, MD	At-Large	X	X	X	X
David Meltzer, MD, PhD	At-Large		X		
Christopher McLaughlin	Ex-Officio	X	X	X	X
Robert Walsh	Ex-Officio	X	X	X	X
Erick Edwards, PhD	Assistant Director, Research	X	X	X	X
Robert Hunter	Policy Analyst/Liaison	X	X	X	X
David Kappus	Assistant Director, Membership	X			
Karl J. McCleary, PhD, MPH	Director, PMR	X	X	X	
Sally Aungier	Liaison, MPSC	X			
Lee Bolton	Liaison, Living Donor Committee	X			
Jacqueline O'Keefe	Performance Analyst Manager	X			
Lori Gore	Liaison, Histocompatibility Committee				X
Jennifer Wainwright, PhD	Research Policy Analyst	X	X		
Leah Edwards	Assistant Director, Research	X	X		
Sarah Taranto	SAS Analyst II	X	X		
John Rosendale	Biostatistician/Senior Performance Analyst	X	X		
Wida Cherikh, PhD	Senior Biostatistician/Team Leader	X	X		
Maureen McBride, PhD	Director, Research	X	X		
Anna Kucheryavaya	Biostatistician	X	X		
Shandie Covington	Liaison, DTAC				X
Franki Chabalewski	Liaison, OPO Committee				X
Elizabeth Sleeman, MHA	Liaison, Pancreas Committee	X			X
Robert Merion, MD	SRTR Representative	X			
Erick Roys	SRTR Representative		X	X	X
Alan Leichtman, MD	SRTR Representative	X	X		
D. Bradley Dyke, MD	SRTR Representative	X	X		
Connie Davis, MD	Living Donor Committee				X
Cynthia Forland, PhD	Living Donor Committee				X