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PUBLIC COMMENT NOTICE

To: OPTN/UNOS members and other interested persons
From: Douglas A. Heiney, Director
Department of Membership Services and Policy Development
Re: OPTN/UNOS policy proposals for public comment
Date: November 20, 2006

Attached for your consideration are four policy proposals that are being issued for public comment. These proposals address issues considered during recent meetings of the Organ Availability Committee, Operations Committee and Policy Oversight Committee.

Following public comment and reconsideration by the appropriate committee(s), these 4 proposals may be offered for consideration by the committee(s) to the OPTN/UNOS Board at its March 23, 2007 meeting.

Please mail, fax, or email your comments on these four proposals to UNOS by January 19, 2007.

Comments on these proposals may also be submitted electronically on the OPTN and UNOS web sites.

UNOS appreciates receiving your response to these important issues.

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## **Background**

The United Network for Organ Sharing (UNOS) is a tax-exempt medical, scientific, and educational organization. UNOS operates the national Organ Procurement and Transplantation Network (OPTN) under federal contract and is responsible for developing an equitable, scientific and medically-sound organ allocation system. The OPTN is further charged with developing by-laws and policies that maximize utilization of organs donated for transplantation, assuring the quality of care for transplant candidates and recipients, and addressing other complex medical issues related to organ transplantation in the United States. All by-laws and policies receive broad input from numerous constituencies including transplant candidates and recipients and family members, donors and donor families, the OPTN membership, and concerned individuals and organizations throughout the United States.

By-Laws and policies are adopted by the OPTN/UNOS Board of Directors pursuant to the UNOS contract with the United States Department of Health and Human Services (DHHS) and after circulation and discussion among organ transplant professionals and patient representatives. These by-laws and policies have been submitted to the Secretary of DHHS and are considered voluntary guidance to OPTN members unless recommended by the Board of Directors and approved by the Secretary of DHHS as OPTN rules and requirements enforceable under Section 1138 of the Social Security Act. Submission of accurate and complete data as specified by the Secretary, which includes data found on OPTN forms and applications approved by the Office of Management of Budget (OMB), are considered enforceable requirements under the OPTN Final Rule. UNOS is responsible for updating these by-laws and policies and for monitoring compliance by OPTN members. Instances of noncompliance with by-laws and policies may lead to disciplinary action, including, for example, designation as a member-not-in-good-standing by the Board of Directors. In addition, instances of non-compliance are reported to the Secretary of DHHS.

Four proposals are being offered for public comment which address issues considered during recent meetings of the Organ Availability Committee, Operations Committee, and Policy Oversight Committee. Following public comment and reconsideration by the appropriate committee(s), these 4 proposals may be offered for consideration by the committee(s) to the OPTN/UNOS Board at its March 23, 2007 meeting.

### **Circulation of Notice**

UNOS maintains a public comment distribution list for policy and by-law proposals. To be included on the distribution list, submit a written request to UNOS at the address below. All policy and by-law proposals issued for public comment are mailed to the distribution list. UNOS typically accepts comments from the public for at least 60 days after publication of the proposals and public hearings on the proposals are arranged if warranted.

### **Comment Deadlines**

The proposals in this document are being issued for public comment on **November 20, 2006**. To be considered, comments must be submitted in writing and sent to UNOS at the following address by **January 19, 2007**.

**United Network for Organ Sharing**  
**700 North 4<sup>th</sup> Street**  
**Richmond, VA 23218**  
**FAX (804) 782-4896**  
**E-mail: [publiccomment@unos.org](mailto:publiccomment@unos.org)**

Comments on these proposals may also be submitted electronically on the OPTN and UNOS Web sites:

<http://www.unos.org/policiesAndBylaws/publicComment/proposals.asp>

<http://www.optn.org/policiesAndBylaws/publicComment/proposals.asp>

## **UNOS Contact Persons**

Inquiries regarding the policy proposals in this document should be made to the appropriate UNOS Regional Administrator at (804) 782-4800. The UNOS Regional Administrators are as follows:

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Region 6 - Alaska, Hawaii, Idaho, Montana, Oregon, Washington

Region 8 - Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming

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Region 11 - Kentucky, North Carolina, South Carolina, Tennessee, Virginia

### **Chrystal Oley-Graybill (graybioe@unos.org)**

Region 5 - Arizona, California, Nevada, New Mexico, Utah

Region 7 - Illinois, Minnesota, North Dakota, South Dakota, Wisconsin

Region 10 - Indiana, Michigan, Ohio

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## I. Summary of Public Comment Items

### 1. **Proposed Modifications to OPTN/UNOS Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer) (Organ Availability Committee)**

This proposal is a modification of the original proposed modification to OPTN/UNOS Policy 3.5.9 and is intended to support a decrease in discards of procured deceased donor kidneys. This modified proposal supports the comments/recommendations of the OPTN/UNOS Operations, Pediatric, Organ Procurement, and Kidney Committees, and Regional comments during the previous public comment period ending October 27, 2006.

The proposal requires standardization in the methodology and reporting of renal biopsies. A tissue sample obtaining at least 25 glomeruli is required. Capture of less than 25 glomeruli will be considered an inadequate biopsy and documentation on the donor form to explain rationale for inadequacy of tissue sample will be required. The wedge technique for renal biopsy obtaining a tissue sample measuring approximately 10mm (length) x 5mm (width) x 5mm (depth) in size is highly recommended. This sample size is calculated to achieve the required glomerular number for reporting (Heptinstall's Pathology of the Kidney 5th ed. By Jennette, Olson, Schwartz, Silvia 1998 Lippincott-Raven p170-171).

Separate standard report forms for frozen and permanent sections will be provided. It is suggested that either a frozen section slide or the specimen taken for biopsy should accompany the kidney. The proposal suggests that the Host OPO with cooperation of the procuring surgeon provide biopsy results for both kidneys of all ECD kidneys and at the request of the surgeon for non ECD kidneys. This modification is intended to standardize renal transplant biopsy procedures and reporting methodologies to allow meaningful analysis.

### 2. **Proposed Modifications to OPTN/UNOS Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials) (Operations Committee)**

The aim of the proposed policy modifications is to address live donor organ packaging and transporting. The proposed policy modifications will provide procedures for packaging and transporting of donated organs not addressed by current policy.

### 3. **Proposed Modifications to OPTN/UNOS Policy 3.1 (Organ Distribution: Definitions) (Operations Committee)**

The objective of the proposed policy modifications is to improve patient safety by requiring verification of UNOS Donor ID number of all organs prior to transplant.

### 4. **Proposed Modifications to Data Elements on UNet<sup>SM</sup> Transplant Recipient Follow-up (TRF) Form (Policy Oversight Committee)**

The proposal would significantly reduce the number of data elements that transplant centers will be required to submit on the Transplant Recipient Follow-up (TRF) form after 5 years post-transplant.

## II. Policy Proposals

In the following proposals, new policy language is underlined. Language to be deleted will show a line through the text. For example, this is how proposed new language will appear and ~~this is how proposed deleted text will appear~~.

### 1. Proposed Modifications to OPTN/UNOS Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer) (Organ Availability Committee)

#### Summary/Performance Objective-Aim

This proposal is a modification of the original proposed modification to OPTN/UNOS Policy 3.5.9 and is intended to support a decrease in discards of procured deceased donor kidneys. This modified proposal supports the comments/recommendations of the OPTN/UNOS Operations, Pediatric, Organ Procurement, and Kidney Committees, and Regional comments during the previous public comment period ending October 27, 2006.

The proposal requires standardization in the methodology and reporting of renal biopsies. A tissue sample obtaining at least 25 glomeruli is required. Capture of less than 25 glomeruli will be considered an inadequate biopsy and documentation on the donor form to explain rationale for inadequacy of tissue sample will be required. The wedge technique for renal biopsy obtaining a tissue sample measuring approximately 10mm (length) x 5mm (width) x 5mm (depth) in size is highly recommended. This sample size is calculated to achieve the required glomerular number for reporting (Heptinstall's Pathology of the Kidney 5th ed. By Jennette, Olson, Schwartz, Silvia 1998 Lippincott-Raven p170-171).

Separate standard report forms for frozen and permanent sections will be provided. It is suggested that either a frozen section slide or the specimen taken for biopsy should accompany the kidney. The proposal suggests that the Host OPO with cooperation of the procuring surgeon provide biopsy results for both kidneys of all ECD kidneys and at the request of the surgeon for non ECD kidneys. This modification is intended to standardize renal transplant biopsy procedures and reporting methodologies to allow meaningful analysis.

#### Background and Significance

During its March 2006 meeting, the Committee reviewed a UNOS Deceased Kidney Donor Biopsy Protocol developed by one of its members. The Committee discussed the protocol, the existing literature on the utility of renal biopsies, and the existing practice of renal biopsies in the transplant community. The Committee agreed that there is minimal information in the literature on biopsy practices and the literature available is inconsistent with regard to correlation of biopsy histology with kidney function. This finding could be attributed to lack of standardization in the methodology of biopsy procurement subsequently affecting an accurate representation of renal histology.

The Committee also reviewed UNOS data summarizing the major reasons for discard of procured kidneys. Biopsies reporting percentage glomerulosclerosis were often used as the sole criteria for discarding recovered kidneys. UNOS data for all kidneys from 1/1/01 to 7/3/04 showed discard rates based on biopsy findings of SCD (24%), DCD (16%), and ECD (41.8%), respectively (see attached exhibit).

Current literature suggests that histology, as it is currently being collected, may not correlate with kidney allograft function. UNOS data for 2000-2004 on biopsies of 5072 standard criteria donors (SCD) showed no correlation between the percentage glomerulosclerosis and the Kaplan-Meier one year graft survival. A similarly poor correlation was shown in 3994 extended criteria donors (ECD). Additionally, a UNOS study (2004) of 257 donors showed there was discordance in the biopsy results of the right and left kidney in 43% of cases (Edwards, et al Transplantation 2004; 77(9): 1411-1415)

With minimal and conflicting information available on renal biopsies, the Committee agreed that both standardization of the biopsy protocol and biopsy documentation requirements on the donor form were warranted.

The following were proposed to become standard for documentation of biopsy information: both kidneys are biopsied, the wedge technique is used, the back table work is standardized in relation to removal of Gerota's fascia, the biopsy is obtained and interpreted (preferably at the donor hospital) prior to initiation of machine preservation, and the a frozen section slide is sent with the kidney to the accepting center for review. Final biopsy results will be performed by the host OPO contracted pathology department and sent to the transplant center.

The rationale for this proposal is that inconsistent and conflicting results on biopsy histology may relate to non standardization of the biopsy technique, sample size, and reporting parameters. The wedge biopsy should be at least 5 mm deep because superficial, sub-capsular biopsies often show a non-representative high proportion of sclerotic glomeruli (Wang HJ, et al Nephrol Dial Transplant 1998; 13: 165-172 ) This is especially true in older (age > 40) kidneys. Biopsies should ideally contain at least 100 glomeruli. An accurate and reproducible ascertainment of percentage glomerulosclerosis can not be made on biopsies containing less than 25 glomeruli. (Wang HJ et al Nephrol Dial Transplant 1998; 13; 165-172; Corwin HL, et al Am J Nephrol 1988; 8: 85-89). Core biopsy can yield acceptable number of glomeruli for analysis, but in the transplant community is more worrisome for uncontrollable bleeding and fistula formation.

The Committee is recommending that a standard biopsy protocol be utilized and the results of the biopsy (when performed) are a component of minimum information for a kidney offer.

### **Policy Proposal**

The Committee is recommending the following modification to Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer)

3.5.9 **Minimum Information/Tissue for Kidney Offer.** The Host OPO must provide the following information to the potential recipient center with each kidney offer:

- (i) Donor name and Donor I.D. number, age, sex, and race;
- (ii) Date of admission for the current hospitalization;
- (iii) Diagnosis;
- (iv) Blood type;
- (v) HLAB, B, Bw4, Bw6, and DR antigens;
- (vi) Current history of abdominal injuries and operations;
- (vii) Pertinent past medical or social history;
- (viii) Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria;
- (ix) Final urinalysis;
- (x) Final BUN and creatinine;
- (xi) Indications of sepsis;
- (xii) Assurance that final blood and urine cultures are pending;
- (xiii) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);
- (xiv) Current medication and transfusion history;
- (xv) Recovery blood pressure and urine output information;
- (xvi) Recovery medications;
- (xvii) Type of recovery procedure (e.g., en bloc); flush solution and method (e.g., in situ); and flush storage solution;
- (xviii) Description of typing material available, including, as a minimum for each kidney:
  - One 7 to 10ml. clot (red topped) tubes, plus
  - 2 ACD (yellow top) tubes
  - 3 to 5 lymph nodes
  - One 2 x 4 cm wedge of spleen in culture medium, if available
- (xix) Warm ischemia time and organ flush characteristics; ~~and~~
- (xx) Anatomical description, including number of blood vessels, ureters, and approximate length of each, injuries to or abnormalities of the blood vessels, ureter(s) or kidney; and

- (xi) The biopsy sample must include greater or equal to 25 glomeruli. It is suggested that either a frozen section slide or the specimen taken for biopsy should accompany the kidney. It is suggested that the Host OPO with cooperation of the procuring surgeon provide biopsy results for both kidneys of all ECD kidneys and at the request of the surgeon for non ECD kidneys utilizing the wedge technique measuring approximately 10 mm (length) x 5 mm (width) x 5 mm (depth).

### **Policy Performance Measures**

OPTN/UNOS staff will collect additional biopsy data on the donor record to ensure the information is reported according to policy. Data including glomeruli count, sclerotic glomeruli count, percent glomerulosclerosis, percent sclerotic glomerulosclerosis, interstitial fibrosis, cellular infiltration, tubular atrophy, vessel arteriosclerosis, hypertensive changes, vessel hyalinosis and rationale for less than 25 glomeruli, if applicable.

### **Resource Analysis**

A key focus of the process of OPTN policy development and implementation is cost and resource efficiency. In an effort to provide the Board of Directors with reasonable expectations regarding the resources that will be required or impacted by policy proposals, an assessment of such resources associated with policy implementation, compliance, and maintenance will be developed for this and every other policy proposal to be presented for Board consideration. The objective is to project impact of the proposed policy upon the following groups as well as staff involved in policy development and implementation:

- OPTN/UNOS Committees
- Transplant Hospitals, OPOs, and Histocompatibility Laboratories
- Candidates, Recipients, and Donors

Such impacts may include, for example, changes in data submission obligations and changes in operational and/or staffing needs that will occur as a result of the modified policy. The change could be either an increase or decrease in these obligations or needs, depending upon the particular proposal and its objective. Understanding expected change in both directions will be important.

We will need your help in assembling these resource analyses. In considering this policy proposal, we, therefore, request your input specifically with respect to your expectations for resource impact upon yourself or institution, as well as the categories of potentially impacted groups listed above. This information will be used in preparing the resource assessment presented to the Committee(s) originating the proposal, Policy Oversight Committee, and Board of Directors.

An assessment of the costs for programming, implementation, ongoing maintenance, and monitoring of proposed forms changes will be submitted once the Committee, Regional, and public comments have been evaluated.

## **2. Proposed Modifications to OPTN/UNOS Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials) (Operations Committee)**

### **Summary/Performance Objective-Aim**

The aim of the proposed policy modifications is to address live donor organ packaging and transporting. The proposed policy modifications will provide procedures for packaging and transporting of donated organs not addressed by current policy.

### **Background and Significance**

In May 2006, the Quality Management Subcommittee of the OPTN/UNOS Operation Committee reviewed a situation submitted by an OPTN member regarding transportation of living donor organs. After considerable discussion and review of the Policy 5.0, the Subcommittee agreed that there is currently insufficient guidance within policy related to packaging and transporting live donor organs, as well as deceased donor organs that fall outside the parameters of current policy. The Quality Management Subcommittee has proposed modifications to Policy 5.0 that would standardize the packaging and transporting of both live and deceased donor organs not addressed in current policy. The basic tenets of the modifications note that when any organ leaves the operating room suite it must be packaged and transported properly; however if an organ does not leave the operating room suite, a second tier of practice must be implemented.

In instances when any organ leaves the operating room suite, the organ(s) must be packaged and labeled in the manner currently defined by policy. If there is a single donor to single recipient scenario within the same operating room suite, the organ(s) must be labeled, but can be transported in an appropriate sterile container. A verification time out before leaving the donor operating room should take place, as well as a time out for second verification of information upon arrival in the recipient's operating room. Additionally, in the event of multiple donors and recipients (i.e., expanded paired exchange) within the same operating room suite, the labeling and double verification time outs are recommended.

The rationale for the proposed modifications is to provide standard packaging and transporting guidance for all donor organs that will increase the likelihood of getting the correct organ to the intended candidate.

### **Policy Proposal**

The Operations Committee considered the following policy modifications to Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials) during their meeting on October 5, 2006. The Committee supported the intent of the policies and unanimously voted (11 For, 0 Against, 0 Abstaining) to submit them for public comment consideration.

### **5.0 STANDARDIZED PACKAGING AND TRANSPORTING OF ORGANS AND TISSUE TYPING MATERIALS**

The following policies address standardized packaging of ~~transplant~~ live and deceased donor organs and tissue typing materials to be transported for the purposes of organ transplantation. When ~~the~~ a deceased donor organ is procured, the Host OPO shall be responsible for ensuring the accuracy of the donor's ABO on the container label and within the donor's documentation. Each OPO shall establish and implement a procedure for obtaining verification of donor ABO data by an individual other than the person initially performing the labeling and documentation requirements put forth in policy 5.2 and 5.3. The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit.

Upon receipt of a live or deceased donor organ and prior to implantation, the Transplant Center shall be responsible for determining the accuracy and compatibility of the donor and recipient ABO and document this verification in compliance with Policy 3.1.2.

**5.1 SPECIMEN COLLECTION AND STORAGE.** Each OPO shall have a written policy established with (a) laboratory(s) approved by the American Society for Histocompatibility and Immunogenetics (ASHI) or THE OPTN. This policy should be determined by the specimen requirements of the typing laboratory and the quality assurance criteria of ASHI or UNOS. The policy shall include specific descriptions of the type of specimen, and medium, in addition to the shipping requirements of same.

**5.2 STANDARD LABELING SPECIFICATIONS.** The Host OPO shall be responsible for ensuring that the outermost surface of the transport box containing organs and/or tissue typing specimen containers must have a completed standardized external organ container label (provided by the OPTN contractor). ~~Any previous labels on the transport container must be removed prior to labeling the box so that only one label exists.~~ The OPO shall label each specimen within the package in accordance with policy. The Host OPO is responsible for ensuring that each tissue or deceased donor organ container that travels outside the recovery facility is labeled appropriately.

In the case of deceased or live donor organs that remain in the same operating room suite as the intended candidate (s), the Host OPO and Transplant Center must develop a standardized approach to ensure identification of the correct donor organ for the correct recipient. Some type of label must accompany the donor organ and documentation must be present in both the donor and recipient charts. A “time out” prior to leaving the donor operating room and an additional “time out” upon arrival in the candidate operating room is recommended.

In the case of live donor organs that travel outside the recovery facility, the Transplant Center(s) involved shall be responsible for ensuring packing is consistent with current Policy requirements and that the outermost surface of the transport box containing the organ must have a completed OPTN/UNOS standardized external organ container label (provided) by UNOS. Any previously used labels on the transport container must be removed prior to labeling the box for transport so that only one label exists. The recovering Transplant Center shall label each specimen within the package in accordance with OPTN/UNOS policy. The recovering Transplant Center is responsible for ensuring that each container that travels outside the recovery facility is labeled appropriately.

**5.2.1** The Host OPO is responsible for ensuring that the Donor I.D. number, donor ABO type, and a secure label identifying the specific contents (e.g., liver, right kidney, heart) are attached to the outer bag or rigid container housing the deceased donor organ prior to transport.

**5.2.2** Each separate specimen container of tissue typing material must have a secure label with the Donor I.D. Number, donor ABO type, date and time the sample was procured, and the type of tissue. The Host OPO is responsible for labeling the materials appropriately.

**5.2.3** The Host OPO is responsible for fixing to the transport container the standardized label completed with the Donor I.D. Number, Donor ABO type, a description of the specific contents of the box, the sender’s name and telephone number, and the Organ Center telephone number.

**5.3 DOCUMENTATION.** ABO results must be provided by the Host OPO in all circumstances during which a deceased donor organ is transported. Properly packaged paperwork containing complete donor information, as described in Policy 2.5.7.1, will be included with the organ transport container in all instances in which the organ is transported.

**5.4 PACKAGING.** In all circumstances during which a deceased donor organ is transported outside the recovery facility, the Host OPO is responsible for packaging, labeling, and handling the organ in a manner which ensures arrival without compromise to the organ(s). Proper insulation and temperature controlled packaging including adequate ice or refrigeration shall be used to protect the organs during transport.

- 5.5 STANDARD ORGAN PACKAGE SPECIFICATIONS.** The re-use of disposable transport boxes is prohibited. If the deceased donor organ is to be commercially shipped, such as with a courier service, commercial airline or charter service, the deceased donor organ must be packaged in a disposable transport box. Coolers are permitted for non-commercial transporting when the organ recovery team is taking the deceased donor organ with them from the donor hospital to the candidate transplant center. The re-use of coolers is permitted. All labels for the previous donor organ must be removed before re-using the cooler. The standard package used by members must have the following properties:
- 5.5.1** A corrugated, wax coated outer container of 200 pound burst strength, or one of equal or greater strength and moisture resistance, must be used.
  - 5.5.2** Inside the moisture resistant outer-container, 1-1/2" thick, expanded polystyrene insulated container or its R-factor equivalent must be used. A closed plastic liner must be placed between the outer container and the polystyrene insulated container to encase the ice.
  - 5.5.3** A closed plastic liner must also be placed inside the polystyrene container to encase the ice. Inside the insulated container, the organ must be protected by a triple sterile barrier and one rigid container which, if sterile, may be considered one of the triple barriers.
    - 5.5.3.1** The rigid container is not required for livers or lungs.
    - 5.5.4** The tissue typing specimen containers must be in a leak proof plastic bag and must not be imbedded in the ice.
  - 5.5.5** The deceased donor paperwork must be in a watertight container. It may be placed in a location specifically designed for the paperwork or inside the outer container, outside of the insulated container.
  - 5.5.6** Accompanying each deceased organ and tissue typing material, a "red top" tube of blood, specifically for confirmation of ABO must be sent to the receiving OPO or transplant center. This tube must be labeled as described in Policy 5.2.2 and placed within the insulated container. The Host OPO is responsible for ensuring that the tube is appropriately labeled.
- 5.6 TRANSPORTATION RESPONSIBILITY.** The Host OPO, as defined in Policy 2.1, is responsible for transportation of deceased donor kidney(s) and tissue typing material to the primary destination designated by the recipient member, (e.g., laboratory, transplant hospital, or OPO). In charter aircraft situations, before the Organ Center will arrange for this mode of transportation, the Host OPO must agree to use a charter aircraft, and it must be determined who will pay for the charter.
- 5.6.1 Transportation Costs Incurred for Renal Organs.** Payment of transportation costs incurred by the OPTN contractor on behalf of a member for a deceased donor kidney that is unconditionally accepted by a member and subsequently forwarded to another member is the responsibility of the member that forwarded the kidney. Payment of transportation costs incurred by the OPTN contractor on behalf of a member for a deceased donor kidney that is conditionally accepted by a member and subsequently forwarded to another member is the responsibility of the Host OPO.
  - 5.6.2 Transportation Costs Incurred for Tissue Typing Material.** Payment of transportation costs incurred by the OPTN contractor on behalf of a member for tissue typing material sent to crossmatch backup recipients for a deceased donor kidney that is conditionally accepted by a member is the responsibility of the member which requested backup for the organ.

- 5.6.3 Transportation Costs Incurred for Non-Renal Organs.** Payment of non-renal deceased donor organ transportation costs incurred by the OPTN contractor on behalf of a member is the responsibility of the member that accepts the organ. Payment of transportation costs incurred by the OPTN contractor on behalf of a member for deceased donor organs that have been accepted and transported, but cannot be utilized for transplantation, also is the responsibility of the member that accepted the organ. If an deceased donor organ is first accepted by one member and subsequently forwarded to another member, payment of transportation costs incurred by UNOS on behalf of a member in forwarding the organ is the responsibility of the member that finally accepts the organ.

### **Policy Performance Measures**

UNOS staff will monitor compliance with the modified policy during scheduled on-site OPO and Transplant Center Audits.

The audit will include verifying documentation that reflects compliance in:

- ABO verification and donor-recipient compatibility prior to implantation
- Validation of the existence of processes for “time outs” for donated organs that remain within the same operating room suite for transplantation

### **Resource Analysis**

A key focus of the process of OPTN policy development and implementation is cost and resource efficiency. In an effort to provide the Board of Directors with reasonable expectations regarding the resources that will be required or impacted by policy proposals, an assessment of such resources will be developed and presented for Board consideration. The objective is to project the impact of these proposed policy modification upon the following groups as well as staff involved in the policy development and implementation:

- OPTN/UNOS Committee(s)
- Transplant Hospitals, OPOs, and Histocompatibility Laboratories
- Candidates, Recipients, and Donors

Such impacts may include, for example, changes in data submission obligations and changes in operational and/or staffing needs that will occur as a result of policy changes. The change could be either an increase or decrease in these obligations or needs, depending upon the particular proposal and its objective. Understanding expected change in both directions will be important.

Feedback related to real or anticipated changes in costs or resources is requested in order to develop these resources analyses. This information will be used in preparing the resource assessment which is presented to the Committee originating the proposal, Policy Oversight Committee, and Board of Directors.

### 3. Proposed Modifications to OPTN/UNOS Policy 3.1 (Organ Distribution: Definitions) (Operations Committee)

#### Summary/Performance Objective-Aim

The aim of the proposed policy modifications is to improve patient safety by requiring verification of UNOS Donor ID number of all organs prior to transplant.

#### Background and Significance

At its meeting on October 5, 2006, the Operation Committee reviewed the request from the Membership and Professional Standards Committee (MPSC) regarding an incorrect, but ABO-identical organ placement error situation. The reported patient safety situation involved a transplant center accepting Kidney A for the first available candidate, Patient A. The transplant center then selected Patient B as backup candidate for Kidney A. Both patients were contacted, and crossmatching was performed while the candidates were en route to the center. Before either patient arrived, the transplant center accepted another kidney (Kidney B) for Patient B. Both kidneys and patients were the same blood type. Negative crossmatch results were obtained for both Patients A and B for Kidney A. Patient B had a negative crossmatch for Kidney B (Patient A was never crossmatched against Kidney B).

Standard “time-out procedures” occurred prior to both surgical procedures which confirmed patient identity, site and side procedure, and position. Additionally the staff verified that the blood types of the candidates and donors were compatible. However, the operating room staff did not confirm the UNOS Donor ID numbers. As a result, Patient A received Kidney B and Patient B received Kidney A. The error was not noted until the next business day. In this case, both patients were treated and later discharged from the center.

The transplant center identified that the following situations contributed to the error:

- both kidneys and both candidates were of the same blood group,
- both kidneys arrived within two hours of each other, and
- there was a lack of communication of the UNOS Donor ID numbers in the operating room.

The Operations Committee discussed the incident and supports the need for policy modifications based upon potential patient safety implications.

The rationale for the proposed modifications is to provide standard procedures for verification of UNOS Donor ID number, in addition to the current ABO verification requirement, for all donor organs prior to transplant.

#### Policy Proposal

The Operations Committee recommends the following policy modifications to Policy 3.1 (Organ Distribution: Definitions), voting unanimously (10 For, 0 Against, 0 Abstaining) to submit them for public comment consideration.

#### 3.1 DEFINITIONS.

The following terms are defined as having the following meanings for the purposes of these policies:

- 3.1.1 OPO.** An Organ Procurement Organization (OPO) is an organization, accepted as a Member, and authorized by the Centers for Medicare and Medicaid Services (CMS) to procure organs for transplantation. For each OPO, CMS defines a geographic procurement territory within which the OPO concentrates its procurement efforts. No OPO is limited to or granted exclusive procurement rights to procure organs in its territory.

- 3.1.2 Transplant Center.** A transplant center is a hospital that is a Member in which transplant are performed. A transplant center may also be called a transplant hospital. It is the responsibility of the transplanting surgeon at the transplant center receiving the organ offer for the surgeon's candidate to ensure medical suitability of donor organs for transplantation into the potential recipient, including compatibility of donor and candidate by ABO blood type. Upon receipt of an organ, prior to implantation, the transplant center is responsible for verifying the recorded donor ABO with the recorded ABO of the intended recipient and UNOS Donor ID number. ~~This action~~ These actions must be documented and ~~is~~ are subject to review upon audit.

### **Policy Performance Measures**

UNOS staff will monitor compliance with the modified policy during scheduled on-site OPO and Transplant Center Audits.

The audit will include verifying documentation that reflects compliance in:

- Verification of UNOS Donor ID number of all organs prior to transplant

### **Resource Analysis**

A key focus of the process of OPTN policy development and implementation is cost and resource efficiency. In an effort to provide the Board of Directors with reasonable expectations regarding the resources that will be required or impacted by policy proposals, an assessment of such resources will be developed and presented for Board consideration. The objective is to project the impact of these proposed policy modification upon the following groups as well as staff involved in the policy development and implementation:

- OPTN/UNOS Committee(s)
- Transplant Hospitals, OPOs, and Histocompatibility Laboratories
- Candidates, Recipients, and Donors

Such impacts may include, for example, changes in data submission obligations and changes in operational and/or staffing needs that will occur as a result of policy changes. The change could be either an increase or decrease in these obligations or needs, depending upon the particular proposal and its objective. Understanding expected change in both directions will be important.

Feedback related to real or anticipated changes in costs or resources is requested in order to develop these resources analyses. This information will be used in preparing the resource assessment which is presented to the Committee originating the proposal, Policy Oversight Committee, and Board of Directors.

#### **4. Proposed Modifications to Data Elements on UNet<sup>SM</sup> Transplant Recipient Follow-up (TRF) Form (Policy Oversight Committee)**

##### **Summary/Performance Objective - Aim**

The proposal would significantly reduce the number of data elements that transplant centers will be required to submit on the Transplant Recipient Follow-up (TRF) form after 5 years post-transplant.

##### **Background and Significance**

In 2006, the OPTN undertook a large scale effort to lessen the data submission burden on transplant centers by reducing the number of data elements that transplant centers are required to submit on OPTN data forms. In June 2006, the Board approved a proposal from the Policy Oversight Committee (POC) that will reduce the data entry burden to centers by approximately 40%. Until the data collection forms are formally revised and approved by the federal Office of Management and Budget (OMB) in 2007, these data elements will still appear on the forms but will not be required.

To continue to reduce the data burden, the Board approved a resolution stating that “the OPTN will address within six months what limited elements other than patient and graft survival will be required for follow up after five years.” As part of a separate OPTN data assessment effort in 2005, OPTN/UNOS organ-specific committees were asked to determine which data elements should be kept on the Transplant Recipient follow-up (TRF) form after 5 years post-transplant. At that time, the Kidney and Pancreas Transplantation Committee asked OPTN/UNOS to retain the following six data elements:

1. Date last seen, transplanted, or death
2. Patient status
3. Cause of death
4. Graft status, cause of graft failure
5. Date of graft failure
6. Serum creatinine

The Liver and Intestinal Organ Transplantation Committee recommended that items 1 – 5 above be retained, as well as presence of and type of malignancy. The Thoracic Committee requested a larger number of data elements that included demographic, patient and functional status, graft function, clinical information, and post-transplant events.

In October 2006, the POC reviewed the list of data elements that will remain on the follow-up forms as a result of after the data reduction project, plus the recommendations made by the Committees in 2005. The POC recommended that the data elements requested by the organ-specific Committees in 2005 remain on the forms. The items retained on the Kidney TRF may be used for net benefit analyses, and thus policy development and assessment. For the liver TRF, the malignancy data were intended to capture recurrence, especially as related to HCC and in light of proposals to modify the HCC criteria. During its October 30, 2006 meeting, the Thoracic Committee refined its list to include only the following three elements in addition to the five requested jointly by the Liver and Kidney Committees:

1. Bronchiolitis obliterans syndrome (for lung only)
2. Coronary artery disease (for heart only)
3. Renal dysfunction (and its follow-on questions concerning creatinine, dialysis, and renal transplant) for all thoracic organs.

The Thoracic Committee is currently analyzing how to incorporate net benefit in the heart allocation system, and these data may be needed for ongoing policy development.

## Proposal

**Table 1 lists** the POC’s recommendations for items to be retained after 5 years post-transplant. In accordance with a resolution approved by the Board in June 2006, the POC will revisit long-term collection of post-transplant malignancy data, after the SRTR has thoroughly assessed the value of collecting these data in terms of quantifying cancer risk and incidence and has determined how long these data should be collected. This should occur no later than June 2008.

**All organ-specific committees should review this list during the public comment period.** Further, since the OPTN Data Reduction project pertained to adult candidates and recipients only, the Pediatric Committee is asked to provide a recommendation for long-term follow-up of pediatric transplant recipients. All requests for items to be retained must be consistent with the OPTN Principles of Data Collection (See attachment 1).

**Table 1. List of Data Elements to be Retained on the TRF After 5 years**

<p><b>Follow-up Elements Common to All Organs</b></p> <p><u>Demographics</u>: Zip code and State <u>Provider/Donor Information</u>: Follow-up center<sup>1</sup> <u>Patient Status</u>: Date last seen, or retransplanted, died, primary cause of death <u>Other Information</u>: Graft status, date of graft failure</p> <p><b>Follow-up Elements: Liver</b> Contributory causes of graft failure<sup>2</sup></p> <p><b>Follow-up Elements: Intestine</b> Primary cause of graft failure</p> <p><b>Follow-up Elements: Kidney</b> Primary cause of graft failure Most recent serum creatinine</p> <p><b>Follow-up Elements: Kidney-Pancreas</b></p> <p>Contributory causes of graft failure (pancreas) Most recent serum creatinine</p> <p><b>Follow-up Elements: Pancreas</b> Contributory causes of graft failure</p> <p><b>Follow-up Elements: Thoracic</b> Bronchiolitis Obliterans Syndrome (Lung forms only) Coronary Artery Disease (Heart forms only) Renal dysfunction (Yes/No) (All Thoracic forms)     If renal dysfunction, creatinine &gt; 2.5 mg/dl     If renal dysfunction, chronic dialysis     If renal dysfunction, renal transplant</p>
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## Impact on HRSA Program Goals and OPTN Strategic Plan

The proposed changes to the forms are not expected to have an impact on the HRSA program goals, which are focused specifically on increasing organ donation, transplantation, and utilization. However, the proposal directly addresses the OPTN Strategic Plan Goal to “improve the OPTN and SRTR data system.” With fewer data elements to collect, centers will be able to focus on a smaller set of data, streamline their processes and consequently improve

<sup>1</sup> For recipient tracking purposes.

<sup>2</sup> Liver follow-up forms do not have a primary cause of graft failure.

the quality of their results. “Improvement of Information Technology Systems” is also a key goal for OPTN President Sue McDiarmid, MD’s, Strategic plan for 2006.

### **Implementation Plans**

According to procedure approved by the Board in June 2005, each proposal that is submitted to the Board must be accompanied by the following:

1. A Resource Analysis
2. A Communications and Education Plan
3. Technical and Functional Specification Documents
4. A Monitoring and Evaluation Plan

These plans are described in general below. When possible, the public comment document will include draft plans. UNOS will develop final plans using information obtained through public comment.

#### Resource Analysis

A key focus of the OPTN policy development and implementation process is cost and resource efficiency. The Board of Directors needs to know how a policy proposal will impact staff resources. To give them a reasonable expectation of this impact, UNOS staff will assess of all resources associated with the implementation, compliance and maintenance of the policy and present a summary to the board before they consider any proposal.

The objective is to project impact of the proposed policy upon the following groups as well as staff involved in policy development and implementation:

- OPTN/UNOS Committee(s)
- Transplant Hospitals, OPOs, and Histocompatibility Laboratories
- Candidates, Recipients, and Donors

For example, a resource analysis impact may include changes in operational or staffing needs that will occur as a result of the new or modified policy. The change could be either an increase or decrease in these obligations or needs, depending upon the particular proposal and its objective. Understanding expected change in both directions will be important.

This proposal is intended to reduce the data reporting burden on the transplant centers. When considering this proposal, please let us know what impact you expect this to have on your personal and institutional resources, as well as how you expect it to impact the groups listed above. UNOS will use this information to prepare the resource assessment for the Policy Oversight Committee and Board of Directors.

#### Communications and Education Plan

Communication and education efforts required for the data reduction proposal are fairly straightforward. The plan to greatly reduce required data after 5 years will reduce the workload for transplant center professionals, so we will focus on communicating the benefits of this change. UNOS will communicate this change through articles in the UNOS Update, blast member emails, postings on the UNOS and OPTN Web sites, and announcements at regional meetings.

#### Technical and Functional Specification Documents

The functional and technical specification documents contain detailed programming changes necessary for UNet<sup>SM</sup> and any other OPTN applications/websites. These will be completed once the Committee, Regional, and public comments have been evaluated and the Board has approved any final modifications. This document will include process and systems changes, as well as any testing and training considerations. These modifications will be incorporated into the 2007 cycle for submission to the Office of Management and Budget (OMB).

### Monitoring and Evaluation Plan

The OPTN will monitor compliance with Policy 7.0 (Data Submission Requirements) as the OPTN Evaluation Plan specifically outlines:

“UNOS programs the UNet<sup>SM</sup> system and notifies transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates transplant centers’ data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer noncompliant transplant centers to the Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with transplant centers during on-site reviews.”

The OPTN Evaluation Plan can be viewed at:

([www.optn.org/SharedContentDocuments/050829.Evaluation\\_Plan\\_-\\_FINAL.pdf](http://www.optn.org/SharedContentDocuments/050829.Evaluation_Plan_-_FINAL.pdf))

## OPTN PRINCIPLES OF DATA COLLECTION (PODC)

- **Primary Goal:** *Improve patient outcomes*
- **Six principles:**
  - Contractual obligations
  - Allocation of organs
  - Policy compliance
  - Policy development
  - Institutional performance
  - Patient care

OPTN



## Resolutions

- \*\* RESOLVED, that the OPTN will, on rare occasions, collect limited but necessary data regarding patient safety in areas in which the OPTN has a unique perspective or responsibility for monitoring patient safety, which may include requirements regarding such from the OPTN contract or the OPTN Final Rule.

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