

OPTN/UNOS OPERATIONS COMMITTEE REPORT SUMMARY

I. Action Items for Board Consideration

- The Board is asked to approve standard procedures for verification of UNOS Donor ID number, in addition to the current ABO verification requirement, for all donor organs prior to transplant to ensure patient safety. (Item 1, Page 3)
- The Board is asked to approve standard packaging and transportation requirements for all donor organs that will increase the likelihood of getting the correct organ to the intended candidate. The proposed policy modifications provide procedures for packaging and transporting donated organs not addressed by current policy, specifically for living organ donations. (Item 2, Page 3)

II. Other Significant Issues

- The Committee is proposing modifications to Policy 4.0 (Disease and Malignancy Screening and Reporting) for distribution for public comment. This revision and expansion of the policy will provide for greater patient safety and better reflect current practice. (Item 3, Page 6)
- The Committee is proposing modifications to Policy 7.4 (Submission of Death Notification Information) for distribution for public comment. This revision of the policy will provide for greater patient safety. (Item 4, Page 12)
- The Committee reviewed the work of the DSA Task Force and through consensus agreed to assume the Tiered Acceptance Criteria project. (Item 10, Page 15)

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**REPORT OF THE
OPTN/UNOS OPERATIONS COMMITTEE MEETING**

**Richmond, VA
June 26, 2007**

**Marlon Levy, MD, Chairman
Richard Hasz, MFS, Vice-Chairman**

The following report represents the Operations Committee's deliberations and recommendations on matters considered by the Committee during its meetings on October 5, 2006 and April 19, 2007.

The Operations Committee met on October 5, 2006 and April 19, 2007 in Chicago, Illinois. Both meetings were led by Dr. Marlon Levy, Chairman.

At the beginning of each meeting, Operations Committee Goals and HHS Program Goals for the OPTN were reviewed by the Committee.

Action Items

1. Reconsideration of Proposed Modifications to Policy 3.1.2 - During the October 2006 meeting, the Committee was requested by Membership and Professional Standards Committee (MPSC) to consider a modification to Policy 3.1.2 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. The Committee supported the MPSC recommendation and voted to distribute the proposed modification for public comment in November 2006.

Committee Vote: 10 For; 0 Against; 0 Abstaining

During the April 2007 meeting, the Committee discussed the public comment responses including proposed modifications from the Policy Oversight Committee (POC) and the potential patient safety impact of the proposed Policy modification (**Exhibit A**). After discussion, the Committee recommended the following for consideration by the Board:

****RESOLVED, the following modifications to Policy 3.1.2, (Transplant Center), having been distributed for public comment and subsequently reconsidered by the Committee, shall be approved and implemented after distribution of appropriate notice and UNetsm programming, if required.**

3.1.2 Transplant Center. A transplant center is a hospital that is a Member in which transplants 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.

Committee Vote: 8 For; 0 Against; 0 Abstaining

2. Reconsideration of Proposed Modifications to Policy 5.0 - During the October 5, 2006 meeting, the Committee considered proposed policy modifications which provide procedures for packaging and transporting donated organs not addressed by current policy, specifically for living organ donations. The rationale behind these proposed modifications is to provide standard packaging and transportation guidance for all donor organs that will increase the likelihood of getting the correct organ to the intended candidate. The Committee voted in favor of including proposed modifications to Policy 5.0 in the Public Comment document dated November 20, 2006.

Committee Vote: 11 For; 0 Against; 0 Abstaining

During the April 2007 meeting, the Committee considered all public comment responses including proposed modifications from the Policy Oversight Committee (POC) (**Exhibit B**). Overwhelming feedback indicated that the proposed policy modifications should not apply in situations when a single donor and transplant recipient are located within the same operating room suite. Also, in accordance with public comment recommendations, policy language was included for labeling machine preserved organs. Therefore, the Committee's discussion yielded the following changes to Policy 5.0.

****RESOLVED, the following modifications to Policy 5.0, (Standardized Packaging and Transporting of Organs and Typing Materials), having been distributed for public comment and subsequently reconsidered by the Committee, shall be approved and implemented after distribution of appropriate notice and UNetsm programming, if required.**

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~~ 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.

5.2 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 (if applicable) and Transplant Center must develop, implement, and comply with a procedure a standardized approach to ensure identification of the correct donor organ for the correct recipient. The Transplant Center must document that the correct organ was identified for the correct recipient-candidate prior to transplant. Some type of label must accompany the donor organ labeling and documentation must be present in both the donor and recipient the candidate 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. Exception: In the case of a single donor organ/organ segment remaining in the same operating room suite as a single intended candidate for a simultaneous transplant, donor organ labeling and "time outs" are not necessary.

In the case of live donor organs that travel outside the recovery facility, the Transplant Center(s) involved shall be responsible for ensuring that packaging is consistent with ~~current Policy~~ the requirements of OPTN Policies 5.2.1 and 5.2.3, 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

to ensure 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. A transport container is defined as a corrugated, wax coated disposable box, cooler, or mechanical preservation cassette or machine.

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 an 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.

Committee Vote: 9 For; 0 Against; 1 Abstaining

Other Significant Items

- Proposed Modifications to Policy 4.0 (Disease Screening and Reporting)** - During the October 2006 meeting, Dr. Jay Fishman, Transplant Infectious Disease Specialist and Chair of the Disease Transmission Advisory Group (DTAG), provided background and rationale for revising and expanding Policy 4.0. He noted that the proposed policy modifications are the result of discussions and data review by the DTAG of cases reported through the Patient Safety System since March 8, 2006.

The Committee discussed the current and proposed policy language. It was recommended that due to the gravity of the proposed changes, the OPO and Organ Availability Committees review the proposed policy modifications and provide feedback to the Committee prior to submitting for public comment. The Committee supported this recommendation with a vote of: 13 For; 0 Against; 0 Abstaining.

During the April 2007 Committee meeting, additional background information was provided to the Committee by Dr. Fishman. He related that recent clusters of donor-derived infection have illustrated potential gaps in both the microbiologic screening of organ donors and in the mechanisms for communication and investigation of transmission events associated with transplantation. A variety of patterns of donor-derived transmissions exist, including:

- Bacteremia and fungemia in donors (often detected after implantation based on blood or other cultures at the time of procurement);
- Active Viral infections: these have included lymphocytic choriomeningitis virus (LCMV), rabies, herpes simplex virus (HSV), West Nile virus (WNV) recently – notably because the symptoms may be absent or masked by coincident neurologic events (e.g., bleed);
- Parasitic infections: clusters of Chagas' disease (*Trypanosoma cruzi*) for which ideal diagnostic tools do not yet exist; and
- Malignancy

He noted that reporting of donor-derived infections is mandated by Policy, but reporting is inadequate and often not timely. The Committee confirmed that the purpose of these modifications is to increase reporting and communication of clinically useful disease transmission information to all recipient centers. Following discussion, the Committee recommended the following:

****RESOLVED**, the Operations Committee supports submitting the following proposed modifications of Policy 4.0 for Public Comment:
Committee Vote: 10 For; 0 Against; 0 Abstaining

4.0 ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS), HUMAN PITUITARY DERIVED GROWTH HORMONE (HPDGH), AND REPORTING OF POTENTIAL DONOR-DERIVED RECIPIENT DISEASES OR MEDICAL CONDITIONS, INCLUDING INFECTION AND MALIGNANCIES, OF DONOR ORIGIN AND SCREENING FOR HUMAN IMMUNODEFICIENCY VIRUS (HIV)

4.1 SCREENING POTENTIAL ORGAN DONORS FOR HIV. All potential donors are to be tested by use of a screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (HIV). If the potential donor's pre-transfusion test for HIV is negative and blood for subsequent transfusions has been tested and found to be negative for HIV, retesting the potential donor for HIV is not necessary. If no pre-transfusion sample of the potential donor's blood is available, the Host OPO (as defined in Policy 2.1) must provide, to the recipient transplant center the screening test results and a complete history of all transfusions received by the donor during the ten (10) day period immediately prior to removal of the organ. Organs from donors with a positive screening test are not suitable for transplantation unless subsequent confirmation testing indicates that the original tests' results were falsely positive for HIV. If additional tests related to HIV are performed, the results of all tests must be communicated immediately to the UNOS Organ Center and all institutions receiving organs from the donor. Exceptions for cases in which the testing cannot be completed prior to transplant are provided in paragraph 4.1.3 below.

4.1.1 Donor History. The Host OPO will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control and Prevention (CDC). The Host OPO must communicate the donor history to all institutions receiving organs from the donor.

4.3 DISCLOSURE OF INFORMATION ABOUT HIV STATUS. UNOS member institutions are obligated ~~urged~~ to comply with state and federal statutes and regulations applicable to the disclosure of personalized data on actual or potential organ donors or recipients.

4.6 SCREENING POTENTIAL ORGAN DONORS FOR TRANSMISSIBLE DISEASES OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES. All potential donors are to be screened for transmissible diseases or medical conditions, including malignancies, through the collection of medical/social history information and laboratory testing when applicable. Medical conditions that should be screened for by history include the presence of malignancies, treated and untreated, or any other known condition that may be transmitted by the donor organ that may reasonably impact the candidate or recipient. In addition, donors shall be tested for recognized transmissible diseases, as defined in policy 2.2.7.1, using screening tests licensed by the FDA for testing these specific diseases in organ donor populations. If additional testing is performed, the results of these tests must be communicated immediately to all recipient institutions. The OPO is responsible for timely follow-up of donor screening tests. Documentation of any suspected or confirmed transmissible disease or medical condition identified prior to or following procurement must be communicated by the Host OPO to all potential recipient centers and the OPTN according to Policy 4.7.

4.6.1 Donor History. The Host OPO will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control. The Host OPO must communicate the donor history to all recipient institutions. This communication should be documented in the donor chart.

4.6.2 Reporting. Known infections or malignant conditions that may be transmitted by the donor organ must be communicated to the transplant centers. These may include, but are not limited to, the following:

4.6.2.1 Active Malignancy

Donors with active malignancies should not be recovered for transplant.

Exceptions:

- Donors with non-metastatic skin cancers:
 - Basal Cell Carcinoma
 - Squamous Cell Carcinoma
- Donors with central nervous system (CNS) malignancies, which have the potential for extra-cranial spread. The OPO must notify all recipient centers of the presence of the following tumors:
 - Astrocytoma
 - Glioblastoma Multiforme
 - Medulloblastoma
 - Malignant Meningioma

4.6.2.2 History of Malignancy

The OPO must notify all recipient centers if the donor has a history of malignancy, which should include the type of malignancy, grade of tumor (if known), prior treatment, and time elapsed since last treatment.

Exception:

- Donors with a medical history of the following malignancies should not be recovered:
 - Melanoma
 - Hodgkin's Disease or Non-Hodgkin's Lymphoma
 - Leukemia
 - Multiple Myeloma
 - Aplastic Anemia and Agranulocytosis

4.6.2.3 Intra-Cranial Hemorrhage

Non-traumatic intra-cranial hemorrhage in non-hypertensive donors may be due to intra-cranial malignant metastases, which have been observed in some infections. Unexplained intra-cranial hemorrhage mandates thoracic and abdominal exploration before recovery of any organs. Any masses palpated or seen should be biopsied for frozen section histopathologic examination.

4.6.2.4 Active Infections.

All recipient centers must be notified by the OPO of any suspected or confirmed active (untreated) infection as soon as test results or epidemiologic information are available. Microbiological assays will not be performed for all conditions in all donors and results may not be available at the time of transplantation. Specific assays may be requested based on unique epidemiologic features. The following infectious conditions must be communicated to the recipient centers:

Viral Infections

- HIV infection (serologic, molecular assay or by history)
- Viremia:
 - Herpes viruses including acute EBV (mononucleosis)
 - Herpes simplex
 - Varicella zoster
 - Cytomegalovirus
 - Other active Viremia
- Active measles, mumps, varicella zoster virus, rubella infections
- Herpes simplex encephalitis or other encephalitis (untreated)
- HTLV-I/II (Serologic or molecular assay)
- Hepatitis A, B, or C
- SARS
- West Nile virus infection or other Arbovirus infection -- active or diagnosed within 6 months:
 - Eastern equine encephalitis virus
 - St. Louis encephalitis
 - Japanese encephalitis virus
 - Dengue
 - Yellow fever
- Lymphocytic choriomeningitis virus (LCMV)
- Rabies
- JC polyomavirus virus infection
- Creutzfeldt-Jacob disease
- Active Viral Pneumonia or viremia

Fungal Infections

- Systemic fungal infection
- Candidemia
- Cryptococcus neoformans
- Histoplasma capsulatum (active)
- Coccidioides immitis (active)

Bacterial Infections

- Untreated bacterial meningitis
- Active Tuberculosis
- Untreated Infection:
 - Pneumonia
 - Meningococcal infection
 - Bacteremia or sepsis syndrome
 - Syphilis
 - Lyme Disease
 - Rickettsial infection

Parasitic Infections

- Active (untreated) infection:
 - Trypanosoma cruzi
 - Strongyloides stercoralis
 - Toxoplasma gondii

- Leishmania spp.
- Babesia spp.
- Malaria spp.
- Ehrlichia spp.
- Pneumocystis carinii

Clinical Syndrome

- Multi-system organ failure due to overwhelming sepsis
 - Toxic shock syndrome
- Untreated intra-abdominal infection
 - Peritonitis
 - Gangrenous Bowel
- Unknown (undiagnosed) infection of central nervous system
 - Encephalitis
 - Meningitis
- Unknown infection of central nervous system (encephalitis, meningitis)
- ~~Suspected Encephalitis~~
- ~~Hepatitis C~~
- ~~Herpes simplex encephalitis or other encephalitis~~
- ~~History of JC virus infection (causes progressive multifocal leukoencephalopathy)~~
- ~~West Nile virus infection~~
- ~~Cryptococcal infection of any site~~
- ~~Rabies~~
- ~~Creutzfeldt-Jacob disease~~
- ~~Other fungal or viral encephalitis~~
- ~~Bacterial meningitis~~
- ~~Infection with HIV (serologic or molecular)~~
- ~~Active viremia: herpes, acute EBV (mononucleosis)~~
- ~~Serologic (with molecular confirmation) evidence of HTLV-I/II~~
- ~~Active hepatitis A or B~~
- ~~Infection by: Trypanosoma cruzi, Leishmania, Strongyloides, Toxoplasmosis~~
- ~~Active Tuberculosis~~
- ~~SARS~~
- ~~Pneumonia~~
- ~~Bacterial or fungal sepsis (e.g. candidemia)~~
- ~~Syphilis~~
- ~~Multi-system organ failure due to overwhelming sepsis, such as gangrenous bowel~~
- ~~Malignancies other active malignant neoplasms,~~
- ~~Melanoma, Merkel cell, including Kaposi's~~
- ~~Hodgkins' disease and non-Hodgkin's lymphoma~~
- ~~Multiple myeloma~~
- ~~Leukemia~~
- ~~Aplastic anemia agranulocytosis~~
- ~~Miscellaneous carcinomas~~
- ~~Any new conditions identified by the CDC as being a potentially communicable disease~~

4.6.3 Exceptions. Organs from donors with a positive screening test or confirmed medical conditions that may be transmittable, with the exception of HIV, may be transplanted at the discretion of the transplanting program with the informed consent of the recipient.

4.6.4 Donor Consent Forms. OPTN member institutions are encouraged to include in each donor consent form a notice that all potential donors will be screened for medical acceptability for organ donation and that results of such tests may be the basis for not using the organ in transplantation.

4.7 POST-TRANSPLANT REPORTING OF POTENTIAL TRANSMISSIBLE DISEASES, OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES. ~~When a transplant program is informed that an organ recipient at that program is confirmed positive for or has died from a transmissible disease or medical condition for which there is substantial concern that it could be from donor origin, the transplant program must notify by phone and provide available documentation, as soon as possible and not to exceed one complete working day, to the procuring OPO. All potential or confirmed donor-derived disease (generally infection or malignancy) transmissions/conditions must be reported to the OPTN via the Patient Safety System in Secure Enterprise. In the event that the system is unavailable, contact the Organ Center and ask for the disease transmission coordinator on-call. The overall intent is to transfer the knowledge/concern Reporting will assure the rapid communication of clinical data from one transplant center the donor OPO to all other transplant centers and to the recipient OPO who have accepted organs from the same identified donor as quickly as possible. The transplant center or OPO originating the concern of transmissibility is responsible for the immediate (within 24 hours) reporting of such data regardless of the status of on-going investigations of possible transmission events. should not wait for all medical documentation that will eventually be available, but communicate that center's concerns through the OPO and OPTN to all other centers involved with that same donor as soon as possible so the other centers could use their medical judgment as to which, if any, investigations or actions need to be performed on their patients.~~

4.7.1 Definitions

4.7.1.1 Procurement: Pre-Transplant Donor Disease Identification

Identified by the OPO:

- during the procurement process and communicated to the transplant center at the time of organ offer and acceptance.
- during the procurement process but after organ(s) have been transplanted.

Identified by the OPO or Transplant Center:

- after procurement was completed but prior to organ transplant.

4.7.1.2 Post-Transplant Donor Disease Identification

Identified by the OPO:

- after procurement and after all organs have been transplanted.
- after notification from a tissue or eye bank or tissue processor after organs have been transplanted.

Identified by a Transplant Center:

- in a recipient at any time post-transplantation of an organ, tissue or eye reported through any communication pathway.

4.7.2 Responsibilities

4.7.2.1 The procuring OPO shall:

- ~~communication of the test results and diagnosis as soon as practicable to any transplant center and tissue bank that received an organ or tissue from the donor who is the subject of the investigation;~~
- Be responsible for reporting clinical information regarding a potential or confirmed donor-derived disease transmission or medical condition to all affected organizations, which may include but are not limited to transplant centers, recipient OPOs, tissue or eye banks and/or public health organizations, and the OPTN. The information may include but is not limited to laboratory, pathology, autopsy, or imaging results, and clinically significant data, symptoms or syndromes which are necessary for clinical management of a recipient. This must occur within 24 hours of the availability of such data.
- ~~m~~Management of the investigation to determine whether the organ donor was diagnosed with a potentially transmissible/detected disease or condition is confirmed and is donor-derived;
- ~~n~~Notificationy the OPTN of the event to the OPTN as soon as possible; and potential or confirmed donor-derived disease transmission/condition within 1 working day of knowledge.

- Provide an initial written report to the OPTN within five (5) working days from the original notification.
- Provide a final written report to the OPTN within thirty (30) working days from the date of the initial written report.
- Contact Public Health organizations as appropriate for all reportable diseases.
- ~~submission of a final written report to the OPTN within 45 days, which specifies the organizations and individuals who were notified, when the notifications occurred, and results of the investigation including test results of the organ recipients who are the subjects of the investigation.~~

4.7.2.2 The OPTN shall:

- ~~Assist the procuring OPO in identifying all organ transplant programs and recipients who receiving organ(s) ed an organ from the affected donor who is the subject of the investigation.~~
- Contact all transplant centers and OPOs involved to confirm that notification of the potential or confirmed donor-derived disease transmission/condition has occurred and necessary clinical information has been communicated.
- Request that any additional diagnostic testing performed at the recipient transplant centers be communicated to the donor OPO and the OPTN.
- ~~The OPTN will monitor the notification process to verify that the procuring OPO and all recipient organ transplant programs have been notified of the disease or medical condition and will request that any additional diagnostic test results be submitted to the procuring OPO with a copy to the OPTN.~~
- UNOS will forward Provide a copy of the OPO's final report submitted by the OPO to the recipient transplant centers and the Division of Organ Transplantation of the Health Resources and Services Administration.

~~Note: The identities of the donor and any organ recipient who are the subjects of the investigation shall remain confidential and all correspondence will refer to the donor and recipients by their donor identification number and recipient social security numbers. Under no circumstances should a transplant program or OPO disclose this information in a manner that is contrary to applicable law.~~

4.7.2.3 The Transplant Center shall:

- Communicate suspected or confirmed donor-derived transmissions within one (1) working day either to the local OPO directly or to OPTN via the Patient Safety System in Secure Enterprise. If reported to the local OPO, the OPO will report such data to OPTN within 24 hours.
- Provide any diagnostic test results or clinically significant data to the local OPO. The OPO will be responsible for reporting such data to OPTN and to the donor OPO within 24 hours. (This information will be used to facilitate clinical management of recipients.)
- Contact Public Health organizations as appropriate for all reportable diseases.

4.7.2.4 Note: The identities of the donor and any organ recipients who are the subjects of the investigation shall remain confidential and all correspondence will refer to the donor and recipients by their donor identification number and recipient social security numbers. Under no circumstances should a transplant program or OPO disclose this information in a manner that is contrary to applicable law.

4.7.3 Exceptions. There are no exceptions to reporting a suspected or confirmed donor-derived disease or medical condition, including malignancies to the OPO, transplant recipient centers or the OPTN.

4. Proposed Modifications to Policy 7.4 (Recipient Death Reporting) - The Committee reconsidered the issue of mandatory reporting of post-transplant adverse events. This issue was first discussed by the Committee during

their May 11, 2006 meeting. From these discussions and further deliberation in October 2006, the Committee focused on whether recipient death soon after transplant should require immediate reporting to the OPTN to improve the surveillance of transmission events. Proposed policy language was considered by the Committee to require reporting to the OPTN all recipient deaths that occur within the first year post-transplant by the transplant center immediately at the time of their notification. Draft policy language was sent to the OPO and Organ Availability Committees for their feedback but neither committee provided comments on the policy proposal.

Following additional discussion during the April 2007 meeting, the Committee recommended that the following proposed policy modifications be distributed for public comment.

****RESOLVED**, the Operations Committee supports submitting the following proposed modifications to Policy 7.7 for Public Comment:

Committee Vote: 10 For; 0 Against; 0 Abstaining

7.4 SUBMISSION OF ORGAN-SPECIFIC TRANSPLANT RECIPIENT FOLLOW-UP AND DEATH FORMS INFORMATION

7.4.1 All recipient deaths that occur within the first year post-transplant must be reported to the OPTN by the transplant center through UNetsm within two working days of their notification.

7.4.2 ~~The appropriate Transplant Recipient Follow-up form~~ After the first year post-transplant, the recipient's death or graft failure must be ~~submitted~~ reported to the OPTN through UNetsm within 14 days of notification of the recipient's death or graft failure.

7.4.2 In cases other than those cited in Policy 7.4.12, all Transplant Recipient Follow-up Forms must be submitted to the organ-specific registry within 30 days of the form generation date.

5. Reconsideration of Proposed Modifications to Policies 3.4.1 and 7.6.1 - During the October 2006 meeting, the Committee reconsidered the proposed policy modifications, and discussed public comment feedback as well as recommendations of the Electronic Organ Placement Working Group, and unanimously supported the following Working Group recommendations with a vote of 12 For; 0 Against; 0 Abstaining:

3.4.1 Time Limit for Acceptance - A transplant center must access donor information within UNetsm within one hour of receiving the initial organ offer notification. Once the appropriate donor information is provided as described in Policies 3.5.9, 3.6.9, 3.7.12, and 3.8.5 a transplant center shall be allowed one hour from the time of accessing the donor information ~~organ offer~~, except as otherwise provided in Policies 3.5.3.5 (Time Limit) and 3.8.1.6.1 (Time Limit), in which to communicate its acceptance or refusal of the organ. After one hour, or shorter period as defined under Policies 3.3.5 and 3.8.1.6.1, the offering entity may offer the organ to the transplant center(s) for the patient(s) listed next in priority ~~by the on the match list UNOS Match System.~~ If either hour elapses without a response, the offer will be considered refused.

7.6.1 Entry and Validation of Offers - ~~Potential recipient refusal reasons for all offers shall be validated.~~ Patient-specific refusal reasons for all offers shall be entered by the OPO and validated by the transplant center using the online procedure available in UNetsm. Entry of patient-specific refusal reasons for all organ offers shall be a shared responsibility of the donor OPO and the transplant center considering the offer. Patient-specific refusal reasons shall be validated by the transplant center using the online procedure available in UNetsm.

Prior to sending the resolution to the Board, the Committee was requested to clarify the proposed policy language. As a result, the following policy language was recommended by the Committee to the December 2006 meeting of the Board of Directors:

****RESOLVED**, that the proposed modifications to Policies 3.4.1 (Time Limit for Acceptance) and 7.6.1 (Entry and Validation of Offers) as set forth below, having been distributed for public comment and

subsequently reconsidered by the Operations Committee and Electronic Organ Placement Working Group, are hereby approved effective December 14, 2006.

3.4.1 Time Limit for Acceptance - A transplant center, or its designee, must access donor information within UNetsm within one hour of receiving the initial organ offer notification. Once the appropriate donor information is provided as described in Policies 3.5.9, 3.6.9, 3.7.12, and 3.8.5 a transplant center shall be allowed one hour from the time of accessing the donor information organ offer, except as otherwise provided in Policies 3.5.3.5 (Time Limit) and 3.8.1.6.1 (Time Limit), in which to communicate its acceptance or refusal of the organ. After one hour, or shorter period as defined under Policies 3.3.5 and 3.8.1.6.1, the offering entity may offer the organ to the transplant center(s) for the patient(s) listed next in priority by the on the match list UNOS Match System. If either hour elapses without a response, the offer will be considered refused.

7.6.1 Entry and Validation of Offers - Potential recipient refusal reasons for all offers shall be validated. Patient-specific refusal reasons for all offers shall be entered by the OPO and validated by the transplant center using the online procedure available in UNetsm. Entry of patient-specific refusal reasons for all organ offers shall be a shared responsibility of the donor OPO and the transplant center considering the offer. The donor OPO is responsible for ensuring that acceptance or refusal information is documented for each organ offer. Patient-specific refusal reasons, not entered by the transplant center or UNOS Organ Center, shall be validated by the transplant center using the online procedure available in UNetsm.

The Board unanimously supported this proposal with a vote of: 38 For, 0 Against, 0 Abstaining

6. Update on OPO Committee Modifications to Policy 3.2.4 Related to Maintaining ABO Documentation - During the October 2006 meeting, the Committee was provided a summary of the OPO/Operations Committees conference call that was held on July 18, 2006 regarding the proposed policy modifications for ABO verification documentation and subsequent Board of Directors approval of the modifications. It was noted that the resulting modifications were consistent with this Committee's opinion.
7. Distance Screening for Pancreas Islet Allocation - During the October 2006 meeting, the Committee was informed that the minimum acceptance criteria for candidates related to distance from the donor center is not used by the match system to screen pancreas islet candidates. Anecdotal examples were provided including: long distance pancreas islet offers that are routinely refused for distance and the associated increased cold ischemia time. It was suggested that expanding the match distance screening to include pancreas islets would streamline the allocation process and screen off centers from the list that would not accept these offers. The Committee voted 10-0-1 in support of including a distance specific field for minimum acceptance criteria for islets cells. The Committee's recommendation will be forwarded to the Pancreas Transplantation Committee for consideration. It was noted during the April 2007 meeting that this programming modification was implemented on January 31, 2007.
8. Policy Implementation Process / Policy Oversight Committee (POC) Requirements - During the October 2006 meeting, Courtney Bland, IT Business Analyst, reviewed with the Committee the Policy Implementation Process and POC requirements. Examples of the prepared materials for proposed Policies 3.4.1 and 7.6.1 were examined and Committee questions were addressed.
9. Consideration of Other Proposed Policies Circulated for Public Comment - The Committee considered current proposed policies, which were included in the Public Comment document dated August 28, 2006 and March 2, 2007.

The document dated August 28, 2006 included 19 proposals, which were considered during the October 2006 meeting. The Operations Committee opinion is shown below for the selected proposals the Committee felt were within their purview:

1. Proposal for National Kidney Paired Donation (KPD) Program (Kidney Transplantation Committee) - The Committee supports this proposal conceptually, realizing its potential good and acknowledging the pilot experience in Region 1.

Committee Vote: 12 For; 0 Against; 0 Abstaining

6. Proposed Modifications to OPTN/UNOS Policy 3.6.11 (Allocation of Livers for Segmental Transplantation) (Liver and Intestinal Organ Transplantation Committee) - The Committee supports the proposed policy modifications in the hopes that further discussion will promote interest in split liver programs and the necessary expertise. The Committee did voice some concern regarding listing criteria and techniques employed to split livers.
Committee Vote: 11 For; 0 Against; 0 Abstaining
8. Proposed Modifications to OPTN/UNOS Bylaws Appendix B Attachment 1, Section VI (Transplant Surgeon and Physician) and Section XII (Transplant Programs) (Liver and Intestinal Organ Transplantation Committee).
Committee Vote: 11 For; 0 Against; 0 Abstaining
17. Proposed Modification of Policy 2.2 (Evaluation of Potential Donors) (Membership and Professional Standards Committee) - The Committee supports the proposed policy modification and would recommend the addition of arterial blood gases to the requirements prior to organ offers for all deceased donors in an effort to optimize donor management.
Committee Vote: 13 For; 0 Against; 0 Abstaining
18. Proposed Modifications to OPTN/UNOS Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer) (Organ Availability Committee) - The Committee agrees that ECD and DCD kidney biopsies, as proposed, are helpful where “clinically indicated.” The Committee also supports a consensus approach to standardize the technique and interpretation for such biopsies.
Committee Vote: 12 For; 0 Against; 0 Abstaining
19. The Proposed Modifications to Appendix B of the OPTN Bylaws (OPO Committee)
Committee Vote: 13 For; 0 Against; 0 Abstaining

The document dated March 2, 2007 included seven proposals, which were considered during the April 2007 meeting. The Operations Committee opinion is shown below for the selected proposals the Committee felt were within their purview:

3. Proposed Modification to OPTN/UNOS Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data) (Living Donor Committee) - The Committee’s consensus was to support the proposal for additional reporting requirements for live donors, but would recommend removing the requirement for organ specific data. However, the Committee recommends reporting for all live donors.
6. Proposed Imminent Neurological and Eligible Death Definition Data Elements (OPO Committee) - The Committee’s consensus was to recommend that the OPO Committee consider including only the data elements necessary to satisfy the OPTN Contract requirements in order to reduce the data burden for OPOs.
10. Tiered Acceptance Criteria - Robert Metzger, MD, DSA Task Force Chair and John Rosendale, UNOS Senior Biostatistician, provided a presentation on the tiered acceptance criteria project that had been guided by the DSA Task Force. Their presentation focused on the background of the proposals; organ-specific data demonstrating the value of various proposed screening processes; and the current status of this project. It was noted that OPTN/UNOS organ-specific committees have been reviewing the proposed tiered acceptance criteria specific to their purview during their spring meetings. Dr. Metzger requested that the Operations Committee assume responsibility for this project since the DSA Task Force was recently disbanded. He also recommended that a subgroup be constituted of past DSA Task Force members and current Operations Committee members to oversee and guide this work. Dr. Levy, with the consensus of the Committee, agreed to assume this project and noted the emerging need for more specific match screening criteria due to the recent implementation of the new DonorNet[®] electronic organ placement system.
11. Disease Transmission and Malignancy Report - During the October 2006 meeting, Joyce Hager, MPH, Patient Safety Specialist, provided a summarized report of all cases since January 1, 2006. The Committee reviewed 42 new cases reported since the previous meeting on May 11, 2006. Eight cases resulted from false positive lab

results. Six cases had confirmed transmissions. There were 24 cases in which transmission was not confirmed. One case was retracted after a second opinion of pathology slides found no evidence of malignancy. Two cases were recipient derived disease. One case was living donor related. A summary of cases divided by malignancy and infection, which included crude incidence rates, was also reviewed.

During the April 2007 meeting, Ms Hager provided a summarized report of all cases from January 1, 2006. The Committee also reviewed cases reported since their last meeting on October 5, 2006. Thirty-three cases were reported during this time period. Five cases were confined to the recipient only or were a result of false positive lab results. A confirmed transmission was noted in only one case. In all other cases transmission was not confirmed. A summary of reported cases during 2006 and 2007 divided by malignancy and infection and the respective number of cases categorized by false positive results, recipient only disease and total reported cases was also reviewed by the Committee.

12. Disease Transmission Advisory Group (DTAG) Composition and Role - During the October 2006 meeting, the Committee discussed the need for expanding the DTAG to include additional adult and pediatric infectious disease and malignancy expertise. During this discussion, new Committee members were provided background information regarding the role of DTAG, a subcommittee of the Operations Committee. The Committee discussed the process and frequency for transmission notification and agreed that this determination should be left for the Advisory Group to decide.

During the April 2007 meeting, the Committee considered progress in expanding Disease Transmission Advisory Group which had occurred since the previous meeting. New members of the DTAG were announced as follows: Dr. Emily Blumberg, Dr. Mike Ison, Dr. Amit Tevar and Dr. Michael Nalesnik, Co-Chair. The Committee was advised that the newly constituted Advisory Group met by conference call on January 22, 2007 and had agreed upon the following Advisory Group goals:

- a. Improve documentation of transmission events
- b. Develop protocols for initiating epidemiologic investigations as appropriate by public health authorities and CDC
- c. Develop protocols for providing clinical guidance, where appropriate
- d. Develop mechanisms for prevention of future events
- e. Analyze data to identify patterns of transmission when sufficient data become available
- f. Educational opportunities

The Committee concurred that these Advisory Group goals were appropriate and attainable and voted 10 For; 0 Against; 0 Abstaining, in support of the goals and the Advisory Group's efforts to monitor potential and confirmed donor related disease transmission events.

A reporting/notification algorithm, data analysis and database development plan was developed for DTAG by the Centers for Disease Control and Prevention (CDC) at the request of the Advisory Group. The proposed algorithm and plan were reviewed and discussed by the Committee. The Committee voted 10 For; 0 Against; 0 Abstaining in support of the algorithm and plan.

The Committee also discussed proposed modifications to Policy 4.0 with respect to the 45 day report requirement for all reported disease transmission events. At this time, there is no distinction between the final report time (45 days) for infectious disease and malignancy reporting. Given the amount of time biologically necessary for malignancies to become clinically apparent, it was proposed that final reports for potential or confirmed malignancy transmissions be submitted at one year after the reported event instead of the 45 days. The Committee discussed the proposal and recommended that this proposed modification be reviewed by the OPO Committee for input and consideration.

13. Patient Safety Situation Report - During the October 2006 meeting, Ms. Hager provided a summarized report of the 11 patient safety situations reported since March 8, 2006. The Committee did not request any additional actions from the reporting institutions. A follow up report of three situations which were reviewed by the Quality Management (QM) Subcommittee during a conference call on July 13, 2006 was also provided. During the QM call, Subcommittee members requested a description of the changes to the reporting institution's Standard Operating Procedures, which were implemented to prevent future patient safety occurrences. These changes were considered and deemed to be appropriate by the Operations Committee. In addition, the Committee reviewed and approved the proposed OPTN process flows for handling reported patient safety

situations. It was decided that situations which were considered critical or resulted in organ wastage should be reported to the Committee within one working day via email.

During the April 2007 meeting, Ms. Hager provided a summarized report of the 13 patient safety situations which had been reported since October 5, 2006. Two situations represented policy violations and were referred to the Department for Evaluation and Quality (DEQ) for further investigation. Two reports of organ wastage due to transportation errors occurred during this time frame. The Committee did not request any additional actions from reporting institutions. However, the Committee requested feedback from DEQ investigations, when available.

14. DonorNet®2007 Update - During the October 2006 and April 2007 meetings, Chris Williams, Director of Technology Services, provided DonorNet®2007 project status reports for the Committee. In each presentation, the Committee was apprised of the status of system implementation and training, with pilot use data being presented during the April 2007 meeting. At both Committee meetings, members asked many questions about the new system and confirmed their support for the new electronic organ placement system.

During the October 2006 meeting, Chairman Levy and Vice Chair Hasz provided an update for the Committee regarding the previous day's Electronic Organ Placement Working Group meeting and the formation of a DonorNet® Rapid Response Task Force, as requested by Dr. Sue McDiarmid OPTN/UNOS President. Ms. Kristi Ross and Mr. Rick Hasz volunteered to participate in the Rapid Response Task Force.

15. Update on New OPTN System Development - During the October 2006 meeting, Berkeley Keck, RN, MPH, UNOS Assistant Executive Director, provided an overview and plans for developing the new OPTN system which will replace the current UNetsm system. Mr. Keck also provided an update during the April 2007 meeting related to progress that had occurred since the last meeting. He noted that an advisory group was being established for this project similar to how the Electronic Organ Placement Working Group guided the DonorNet®2007 project. In similar fashion, this new advisory group will report to the Operations Committee which will act as the sponsoring committee for the new system's development.

16. Directed Donation - During the April 2007 meeting, Courtney Bland, IT Business Analyst, presented information to the Committee regarding current directed donation processes and challenges. The Committee was presented with background from the Final Rule and OPTN Policy. Currently, only candidates who appear on the match list receive organ offers. However, depending on their listing criteria and the organ allocation policy requirements, directed donation candidates may be screened off a match list for ABO incompatibility or willingness to accept HCV positive organs. The Committee questioned how often directed donation occurs each year for which this number was not known at the time of the meeting. After discussing the patient safety implications of the current processes, the Committee agreed to establish an implementation subcommittee to address this issue. Dr. Marlon Levy, Dave Bekofsky and Lee Langley volunteered to participate in the subcommittee.

17. Multiple Organ Allocation - Ms. Bland provided a presentation during the April 2007 meeting related to situations in which a single candidate is actively listed on the waitlist for more than one organ type for which they prefer to receive both organs from the same donor. However, in these situations, the candidate may also receive isolated organ offers for only one organ when both are needed. Currently, the UNetsm system can not differentiate these offers since policy requires that the candidate be listed in active status on each organ-specific list. The Committee briefly discussed this issue and agreed to establish a special work group to assist UNOS staff with resolving these issues. It suggested that recommendations from this group could be included in the design of the new OPTN system. The following members volunteered to participate in the work group: Rick Hasz, Lee Langley, and Laine Krisiunas.

18. Center Level Listing Defaults - During the April 2007 meeting, Ms. Bland updated the Committee regarding the status of removing center levels listing defaults from the Waiting list toward the goal of improving candidate-level match screening. She reported that the ability to apply center-level organ acceptance criteria to listed candidates was removed for liver, intestine and thoracic organs in January 2007. Currently, kidney, kidney-pancreas and pancreas will retain this option since the Kidney and Pancreas Transplantation Committees have not yet fully reviewed and approved of this change.

19. Organ Transportation/Organ Wastage - During the October 2006 meeting, the Chairman shared Dr.

McDiarmid's request for the Operations Committee to address organ wastage issues. In an effort to monitor these issues, the Committee had been and continues to review reports from the Organ Center detailing transportation errors/near-misses and data provided by the UNOS Research Department regarding reasons organs are not recovered and not transplanted. Additionally, it had been the QM Subcommittee's previous recommendation that a survey be distributed to OPO Executive Directors and quality assurance personnel in order to gather data on transportation errors and near-misses experienced outside the scope of the Organ Center. The draft survey, used to capture transportation failure data prospectively for three months, was also reviewed and approved by the Committee.

It was reported in the April 2007 meeting that Ms Hager had distributed the organ wastage survey to OPO Executive Directors and quality assurance personnel to collect occurrences between January 1, 2007 and March 31, 2007 for organs that were wasted or potentially wasted due to transportation issues. Twenty-four OPOs responded to the survey and preliminary results were provided verbally for the Committee. The information collected demonstrated delays in 12 transplants and eight organs wasted during the data collection period. The Committee requested additional information regarding the type of organs wasted in each event. This information will be provided to the Committee during the October 2007 meeting.

20. Match List Re-running - During the October 2006 and April 2007 meetings, the Committee reviewed and discussed data prepared by Leah Edwards, PhD, UNOS Assistant Director Research. As requested by the Committee during the May 2006 meeting, the data were presented at a high level by region and OPO. The Committee requested additional information regarding consequences to patients when the match list is re-run. It was decided that match list re-run information will be provided for the Committee annually as an informational item.
21. Organ Packaging Labels - During the October 2006 meeting, the Committee discussed the idea of including a secondary organ labeling system to be used on internal packaging to supplement the current external labels on the box and sterile bags. The idea was to insert a second water-proof label within the sterile packaging to provide an additional means of identification in cases where the external labels may not be present or may potentially be incorrect. Dr. Michael Hagan and Mike Kelly agreed take an informal poll of the AOPO QI Council and report back to the Committee on current practices, as some OPOs are already using a secondary labeling procedure.
22. Review of E-Quality Draft Newsletter - During the October 2006 meeting, Ms. Hager presented the draft design for the E-Quality newsletter. The Committee approved the design and deliberated on the newsletter's content, which may include Highlights of New Regulations, Case Studies, Lessons Learned, and Top Three Errors Reported. David Bekofsky, Michael Hagen, Mike Kelly, Nancy Knudsen, Laine Krisiunas, Lee Langley, and Melissa Zinnerman volunteered to work with UNOS Staff on development of the quarterly newsletter.

During the April 2007 meeting, the draft newsletter which had been approved by the committee volunteers was provided to the Committee for review and discussion. It was noted that each newsletter will highlight a patient safety situation in a complete case study format. Ms. Hager will finalize the newsletter draft with an expected circulation to members this spring.

23. Status Report on ABO Verification Policies - During the October 2006 and April 2007 meetings, Ms. Edwards provided the Committee with data reports generated from the candidate waitlist demonstrating the number and percent of candidates and donors who have had their ABO changed in UNetsm since system requirements for double verification of ABO by two separate system users was implemented on June 30, 2004. The Committee agreed that the incidence of ABO change is stable and within an acceptable level. They opined that the ABO verification policies and system requirements appear to be effective. This data will continue to be reported at each future meeting as informational.
24. News Release Regarding Italian Patients Receiving HIV Positive Organs - During the April 2007 meeting, the Committee received a news story relating the transplanting of HIV infected organs into recipients. The Chair shared that a root cause analysis indicated that there were testing errors and that the lab test was incorrectly conducted. The assay results were negative as a result of the erroneous test. Ultimately, the PCR testing proved positive and organ recipients sero-converted.
25. Deceased Donors with CNS Malignancies - At the April 2007 meeting, the Committee was provided with a

copy of a presentation regarding CNS tumor donors. Myron Kauffman, MD, UNOS Medical Director had presented these data at the 2006 World Transplant Congress. These donors are considered an underutilized organ source.

26. Vessels Recovered with Organs - During the October 2006 meeting, the Committee was informed of the recent withdrawal of the Final Rule and supplied with the Federal Register notification. Subsequently at the April 2007 meeting, the Committee received the March 12, 2007 Federal Register Notice – Blood Vessels Recovered with Organs and Intended for Use in Organs.

OPTN/UNOS OPERATIONS COMMITTEE MEETING
Chicago, Illinois

Name	Position	<u>October 5,</u> <u>2006</u>	<u>April 19,</u> <u>2007</u>
Marlon Levy, MD	Chair (Region 4)	x	x
Richard Hasz, Jr., MFS	Vice Chair (Region 2)	x	x
Laine Krisiunas, BS, MBA	Region 1	x	x
Lee Langley, RN	Region 3	x	x
Rebecca Menza, RN	Region 5		
Kristi Ross, BSN, RN	Region 6	x	
Melissa Zinnerman, RN	Region 7	x	x
Martin Zamora, MD	Region 8	x	
David Bekofsky, MS	Region 9	x	x
Michael Hagen, DO	Region 10	x	x
Nancy Knudsen, MD	Region 11	x	
William Chapman, MD	At Large		
Jay Fishman, MD	At Large	By phone	x
Barry Friedman, RN, BSN, MBA	At Large	x	x
Daniel Hayes, MD	At Large		
Mike Kelly	At Large	By phone	
Warren Rosenblum, MD	At Large	x	x
Laurel Williams, RN, MSN	At Large		
Ginny McBride, RN, MPH, CPTC	Ex. Officio	By phone	

UNOS staff attending:

Chris Williams, RN, CPTC	Committee Liaison
Gloria Taylor, RN, MA, CPTC	Committee Liaison
Berkeley Keck, RN, MPH	Asst. Executive Director, Information Technology
Joyce Hager, MPH	Patient Safety Specialist
Leah Edwards, PhD	Assistant Director, Research
Courtney Bland	IT Business Analyst

Guests (April 19, 2007):

Robert Metzger, MD	Past Chair DSA Task Force
John Rosendale	Senior Biostatistician