

**OPTN/UNOS Operations and Safety Committee
to the Board of Directors
November 14-15, 2011
Atlanta, GA**

Summary

I. Action Items for Board Consideration

- The Board of Directors is asked to approve modifications to Policy 5.10.1 (Vessel Recovery and Transplant) and Policy 5.10.2 (Vessel Storage) that would restrict storage of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels when they are not transplanted during the original transplant procedure. (Item 1, Page 3)
- The Board of Directors is asked to approve a proposal requiring Organ Procurement Organizations (OPOs) to perform a second determination ABO subtyping test when a donor is identified as non-A1 or non-A1B. Modifications are proposed to Policies 3.1.2 (Transplant Center), 3.1.13 (Definition of Directed Donation), 3.2.4 (Match System Access), 3.5.9.1 (Essential Information for Kidney Offers), 3.6.2 (Blood Type Similarity Stratification/Points), 3.6.9.1 (Essential Information Category), 3.7.12.1 (Essential Information), 3.8.2.2 (Essential Information for Pancreas Offers), 5.1.3 (Mechanical Preservation Machine), 5.3 (External Labeling Requirements), 5.4.1 (Solid Organ), 5.4.2 (Tissue Typing Materials), 5.4.3 (Vessels), 5.5.1 (Documentation Accompanying the Organ), 5.6.1 (Verification of labeling and documentation for deceased donor organs or vessels), 5.7 (Verification of Information Upon Receipt of an Organ), 5.8.2 (Blood for ABO Confirmation), 5.10.2 (Vessel Storage), 12.3.1 (ABO Identification), 12.3.2 (ABO Subtype Identification), 12.7, 12.7.2, 12.7.3, and 12.7.4 (Responsibility of Transport of Living Donor Organs), 12.8.1.1 (Reporting Requirements), and UNOS Bylaws, Appendix B, Attachment IIA, Section I (ABO Blood Group Determination) (Item 2, Page 5)

II. Other Significant Items

- The Committee reviewed the work of the Patient Safety Planning Development (PSPD) subcommittee in the development of a patient safety newsletter, proposed enhancements to the safety situation reporting system, and data reviewed for transportation failures and near misses and labeling errors. (Item 3, Page 15)
- The Committee reviewed and discussed ABO verification compliance and development of a standardized checklist. (Item 5, Page 16)
- The Committee discussed developing an organ tracking and traceability system that would link organs allocated with donor risk that is identified. (Item 6, Page 17)
- The Committee reviewed the work of the Effective Screening Work Group (ESWG) and its educational initiatives to the community over the past six months. (Item 7, Page 18)
- The Committee considered applicable public comment proposals to be distributed September 16, 2011. (Item 8, Page 19)

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OPTN/UNOS Operations and Safety Committee
Report to the Board of Directors
November 14-15, 2011
Atlanta, Georgia

Phillip C. Camp, Jr., M.D. – Chair
Jean Davis – Vice Chair

This report represents the OPTN/UNOS Operations and Safety Committee's (OSC) discussions and deliberations during its meeting held in Chicago, Illinois on September 15, 2011.

- 1. Vessel Recovery, Storage, and Transplant** – The Committee considered a proposal from the Vessel Policy Work Group to restrict storage of hepatitis B surface antigen positive and hepatitis C antibody positive extra vessels when they are not used in the original transplant procedure for the intended recipient. A member reviewed with the committee a data analysis completed during the development of the proposal. These data showed that there could be a potential for approximately one episode of vessel shortage within any given donation service area (DSA) within a one year period of time. The analysis assumed that there would be sharing of vessels by transplant centers within the DSA as is currently allowed by policy. Public comment feedback to the proposal was again reviewed. As a result of feedback the Committee had modified the proposal to allow storage of these vessels but only for use in the intended recipient which would require a special label and process for handling. The proposal was to go to the Board for approval in June 2011, but prior to this meeting, UNOS leadership and several Board members expressed their concerns over the significant changes to the requirements for storage and the addition of labeling requirements. The Board approved the time-out provision proposed in policy 5.10.1 and requested the committee to send the amended policy language in 5.10.2 back out for public comment or to re-consider its recommendations for storage and bring the original proposal for consideration.

After the work group's review of the Board resolution to the proposal, it discussed the proposed recommendations and data reviewed during the development of the proposal. The group is again recommending to the committee to send the original proposed policy language to the Board for approval in November 2011. The work group noted that the transmission of hepatitis C that began the discussions of and development of vessel storage restriction, happened despite appropriate labeling of a hepatitis C antibody positive vessel. Now that the Board has approved the time-out prior to implanting a vessel to verify that the vessel is compatible with the recipient, restriction of storage of hepatitis positive vessels will ensure the safety of the recipient when stored vessels are used.

Although instances are rare, surgeons on the Committee discussed that lack of vessel availability has the potential for a recipient death and other conduits are not ideal. It was agreed that inadvertent transplant of a hepatitis positive vessel was not an ideal outcome, but death or re-listing for transplant could potentially take place if a vessel is not available for vascular reconstructions after the original transplant procedure. Most of the comments were related to assessing the effectiveness of the implemented time-out over time rather than restricting the storage of extra vessels.

The Committee discussed the February 2011 publication of the Centers for Disease Control and Prevention's (CDC) Morbidity and Mortality Weekly Report (MMWR) that outlined recommendations for the practice of storing and transplanting vessels from hepatitis positive donors. A member commented that it would be high risk for centers not to implement the recommendations from a public health agency especially now that new guidelines for high risk donors are being proposed by the United States Public Health Service (USPHS).

After careful review, the Committee voted to recommend the Vessel Policy Work Group's proposed policy to the Board of Directors at its November 2011 meeting for approval (**Exhibit A**). Committee vote: 15 For, 3 Against, and 0 Abstentions.

*****RESOLVED, that Policy 5.10.1 (Vessel Recovery and Transplant) and Policy 5.10.2 (Vessel Storage) shall be modified as set forth below, effective pending notice to the membership:**

5.10.1 Vessel recovery and transplant

- The consent forms used by the recovering OPO must include language that indicates that vessels will be used for transplant.
- The vessels cannot be used other than for the implantation or modification of a solid organ transplant.
- Vessels can be shared among transplant centers. If sharing occurs between transplant centers, the implanting program must submit to the OPTN a detailed explanation justifying the sharing. The justification will be reviewed by the Membership and Professional Standards Committee (MPSC). The implanting transplant program must notify the OPTN of subsequent disposition of the vessel(s).
- If the transplant center stores vessels and subsequently uses the vessels for the intended recipient or another transplant recipient, the OPTN must be notified.
- ~~If vascular conduits from donors with positive serology for hepatitis are subsequently used in other than the intended recipient, the implanting transplant center must provide a detailed explanation to the OPTN for the use of this conduit. The explanation will be reviewed by the MPSC.~~
- The transplant center must verify the ABO, all serology results, container contents, date of expiration, and the UNOS Donor ID of the vessel with the ABO and all serology results of the recipient prior to implantation. The documentation of this verification must be maintained within the recipient medical record and made available to the OPTN contractor upon request.

5.10.2 Vessel storage

The Transplant Center must designate a person to monitor and maintain records, destroy, and notify the OPTN of outcome and/or use of vessels. This designated person must maintain information on all donor vessels including monitoring and maintaining all records relating to the use and management of donor vessels (e.g. subsequent positive serology testing, monitor inventory of stored vascular conduits). This person must monitor the refrigerator, ensure records are up to date and available with the conduits, destroy the vessels when expired, and notify the OPTN of its use or disposal.

- Hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels may not be stored for subsequent use.
- The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).
- The vessels must be stored in a rigid, sterile sealed container labeled with the recovery date, ABO, serology, container contents, and the UNOS Donor ID for tracking. The appropriate packaging of vessels should be completed in the operating room. Label should clearly state for use in organ transplantation only.
- The vessel(s) must be stored in a secured refrigerator with a temperature monitor and maintained within a range of 2 - 8 degrees Celsius.

- There must be daily monitoring of the vessel(s) with documented security and temperature checks by the transplant center.
- The vessel(s) can be stored up to a maximum of 14 days from the original recovery date.
- The transplant center must maintain a log of stored vessels.
- The transplant surgeon must have around the clock access to the donor information prior to using the donor vessel(s) in a recipient other than the intended recipient.

2. **ABO Subtyping Policy Proposal** – The Committee reviewed public comment on the proposed ABO subtyping recommendations developed by the ABO Subtyping Work Group. The proposed policies were sent for public comment in March 2011. The Committee also discussed and agreed with a proposal to further define subtyping field names in UNetSM, as the system notes that donors that are non-A₁ are designated as A₂ which may be inaccurate as there are multiple subtypes. After review of the comments and the work group’s response to the comments, the Committee voted to recommend the following proposed policy for consideration by the Board of Directors at its November 2011 meeting (**Exhibit B**). The Committee voted: 20 For, 0 Against, and 0 Abstentions.

*****RESOLVED, that policies 3.1.2 (Transplant Center), 3.1.13 (Definition of Directed Donation), 3.2.4 (Match System Access), 3.5.9.1 (Essential Information for Kidney Offers), 3.6.2 (Blood Type Similarity Stratification/Points), 3.6.9.1 (Essential Information Category), 3.7.12.1 (Essential Information), 3.8.2.2 (Essential Information for Pancreas Offers), 5.1.3 (Mechanical preservation machine), 5.3 (External Labeling Requirements), 5.4.1 (Solid Organ), 5.4.2 (Tissue Typing Materials), 5.4.3 (Vessels), 5.5.1 (Documentation accompanying the organ), 5.6.1 (Verification of labeling and documentation for deceased donor organs or vessels), 5.7 (Verification of Information Upon Receipt of an Organ), 5.8.2 (Blood for ABO Confirmation), 5.10.2 (Vessel Storage), 12.3.1 (ABO Identification), 12.3.2 (ABO Subtype Identification), 12.7, 12.7.2, 12.7.3, and 12.7.4 (Responsibility of Transport of Living Donor Organs), 12.8.1.1 (Reporting Requirements), and UNOS Bylaws, Appendix B, Attachment IIA, Section I (ABO Blood Group Determination), shall be modified as set forth below, effective pending notice to the membership:**

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 and subtype (when used for allocation). Upon receipt of an organ, prior to implantation, the transplant center is responsible for verifying the recorded donor ABO and subtype (when used for allocation), with the recorded ABO and subtype (when used for allocation) of the intended recipient and UNOS Donor ID number. These actions must be documented and are subject to review upon audit.

[...]

3.1.13 Definition of Directed Donation – OPOs are permitted to allocate an organ(s) to a specific transplant candidate named by the person(s) who authorized the donation unless prohibited by state law. All recipients of a deceased donor organ(s) from a directed donation must be added to the waiting list prior to transplantation.

When the candidate does not appear on at least one of the deceased donor's match runs for at least one organ type, the transplant center must document the reason why the candidate does not appear and ensure that the organ is safe and appropriate for the candidate. The transplant center must maintain all related documentation and provide written justification to the OPTN contractor upon request. The written justification must include:

- the rationale for transplanting the candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run;
- the center is willing to accept an ECD or DCD organ, as applicable; and
- documentation that the transplant center verified suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
 - ABO;
 - ABO subtype when used for allocation;
 - Serologies;
 - Donor HLA and candidate's unacceptable antigens;
 - Height; and
 - Weight.

[...]

3.2.4 Match System Access. OPOs are required to use the Match System (UNetSM) for the allocation of all deceased donor organs. The Host OPO must enter required information about the donor as required by the following Policies:

- Policy 3.5.79 (Minimum Information/Tissue for Kidney Offer),
- Policy 3.6.9 (Minimum Information for Liver Offers),
- Policy 3.7.912 (Minimum Information for Thoracic Organ Offers),
- 3.8.2.2 (Essential Information for Pancreas Offers),

and execute the Match System to determine organ allocation priorities. Such information must be entered into the Match System for all deceased donors.

- **ABO Typing.** ~~To ensure the accuracy of the donor's ABO, the OPO shall be responsible for two separate determinations, either 1) two samples sent to two labs, or 2) two samples from separate draws sent to the same lab of the donor's ABO type prior to incision and for ensuring the accuracy of the donor's ABO data. The OPO shall maintain documentation that such separate verification~~ the an initial and confirmatory second determination tests ~~has~~ has taken place and make such documentation available for audit. Each OPO shall establish and implement a procedure for utilizing ~~the~~ ABO source documents for on-line verification of donor ABO data by an individual other than the person initially entering the donor's ABO data in UNetSM.
- **ABO Subtyping.** When a blood type A (as required by policy 2.2.4.1) or AB donor is subtyped and found to be non-A₁ (negative for A₁) or non-A₁B (negative for A₁B), the OPO must complete a second confirmatory determination subtype test to determine ~~assess the accuracy of the result. Blood samples for the initial and confirmatory second determination subtype tests must be taken on two separate occasions~~ assess the accuracy of the result. Blood samples for the initial and confirmatory second determination subtype tests must be taken on two separate occasions ~~determinations, either 1) two samples sent to two labs, or 2) two samples from separate draws sent to the same lab. Subtype testing must be performed only~~

on pre-transfusion specimens. The two test results must indicate the same subtype before a match can be run using the subtype to allocate organs. When two pre-transfusion samples are not available, or the initial and ~~confirmatory~~ second determination test results do not indicate the same subtype, the donor must be allocated based on the primary blood type ~~A or AB~~, and the subtype should not be entered into UNetSM. The OPO shall maintain documentation that the initial and ~~confirmatory~~ second determination tests have taken place and make such documentation available for audit. Each OPO shall establish and implement a procedure for two individuals to verify the accuracy of the initial and ~~confirmatory~~ second determination subtyping test results by utilizing both ABO subtyping source documents and document that this process has taken place.

Organs shall be allocated only to candidates who appear on a match run. In the event that an organ has not been placed after the organ has been offered for all potential recipients on the initial match run, the Host OPO may give transplant programs the opportunity to update their transplant candidates' data, and the Host OPO may re-run the match system. In any event, the organ shall be allocated only to a candidate who appears on a match run.

If the transplant center deems it necessary to transplant a candidate who does not appear on at least one of the deceased donor's match runs for at least one organ type, such as in the event of a directed donation or to prevent organ wastage, the transplant center must maintain all related documentation and provide written justification to the OPTN contractor upon request. The written justification must include:

- rationale for transplanting a candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run;
- the center is willing to accept an ECD or DCD organ, as applicable; and
- documentation that the transplant center verified suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
 - ABO;
 - ABO subtype when used for allocation;
 - Serologies;
 - Donor HLA and candidate's unacceptable antigens;
 - Height; and
 - Weight.

For all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If an organ is accepted for a candidate who ultimately is unavailable to receive the transplant at his/her listing transplant center in the organ allocation unit to which the organ is being distributed, then the organ shall be released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local OPO level must be done according to the match run. The final decision whether to use the organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of that candidate. This will allow physicians and surgeons to exercise judgment about the suitability of the organ being offered for the specific candidate. If an organ is declined for a candidate, a notation of

the reason for the decision refusing the organ for that candidate must be made on the appropriate form and promptly submitted.

[...]

3.5.9.1 Essential Information for Kidney Offers. 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;
- (i) Blood type;
- (ii) ABO subtype when used for allocation;
- (v) HLA A, B, Bw4, Bw6, C, DR and DQB antigens. When reporting DR antigens, DRBI, and DRB3/4/5 must be reported. The lab is encouraged to report splits for all loci as shown in Appendix 3A;
- (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) Serologies as indicated in 2.2.4.1 qualified specimens preferred as noted in Policy 2.2.3.1);
- (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) tube for ABO Verification, 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

[...]

3.6.2 Blood Type Similarity Stratification/Points. For Status 1A and 1B transplant candidates, those with the same ABO type as the liver donor shall receive 10 points. Candidates with compatible but not identical ABO types shall receive 5 points, and candidates with incompatible types shall receive 0 points. Blood type O candidates who

will accept a liver from a non-A₁ (~~negative for A₁ subtype, (e.g. A₂)~~) blood type donor shall receive 5 points for ABO incompatible matching. Within each MELD/PELD score, donor livers shall be offered to transplant candidates who are ABO-identical with the donor first, then to candidates who are ABO-compatible, followed by candidates who are ABO-incompatible with the donor.

[...]

3.6.9.1 Essential Information Category. When the Host OPO or donor center provides the following donor information, with the exception of pending serologies, to a recipient center, the recipient center must respond to the offer within one hour pursuant to Policy 3.4.1 (Time Limit for Acceptance); however, this requirement does not preclude the Host OPO from notifying a recipient center prior to this information being available:

- (i) Donor name and Donor I.D. number, age, sex, race, height and weight;
- (ii) ABO type;
- (iii) ABO subtype when used for allocation;
- (iv) Cause of brain death/diagnosis;
- (v) History of treatment in hospital including current medications, vasopressors and hydration;
- (vi) Current history of hypotensive episodes, urine output and oliguria;
- (vii) Indications of sepsis;
- (viii) Social and drug activity histories;
- (ix) Vital signs including blood pressure, heart rate and temperature;
- (x) Other laboratory tests within the past 12 hours including:
 - (1) Total Bilirubin
 - (2) ALT
 - (3) INR (PT if INR not available)
 - (4) Alkaline phosphatase
 - (5) WBC
 - (6) HH
 - (7) Creatinine;
- (xi) Arterial blood gas results;
- (xii) Serologies indicated in 2.2.4.1 (qualified specimens preferred as noted in Policy 2.2.3.1).

[...]

3.7.12.1 Essential Information. The Host OPO or donor center must provide the following donor information to the recipient center with each thoracic organ offer:

- (i) The cause of brain death;
- (ii) The details of documented cardiac arrest or hypotensive episodes;
- (iii) Vital signs including blood pressure, heart rate and temperature;
- (iv) Cardiopulmonary, social, and drug activity histories;
- (v) Serologies as indicated in 2.2.4.1 (qualified specimens preferred as noted in Policy 2.2.3.1);
- (vi) Accurate height, weight, age and sex;

- (vii) ABO type;
- (viii) ABO subtype when used for allocation;
- (ix) Interpreted electrocardiogram and chest radiograph;
- (x) History of treatment in hospital including vasopressors and hydration;
- (xi) Arterial blood gas results and ventilator settings; and
- (xii) Echocardiogram, if the donor hospital has the facilities.

The thoracic organ procurement team must have the opportunity to speak directly with responsible ICU personnel or the on-site donor coordinator in order to obtain current first-hand information about the donor physiology.

[...]

3.8.2.2 Essential Information for Pancreas Offers. The Host OPO or donor center must provide the following donor information, with the exception of pending serologies, to the recipient center with each pancreas offer:

1. Donor name and Donor I.D. number, age, sex, race and weight;
2. Date of admission for the current hospitalization;
3. Diagnosis;
4. Blood type;
5. ABO subtype when used for allocation;
6. Current history of abdominal injuries and operations including pancreatic trauma;
7. Pertinent past medical or social history including pancreatitis;
8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria;
9. Indications of sepsis;
10. Serologies as indicated in Policies 2.2.4.1 and (qualified specimens preferred as noted in Policy 2.2.3.1):
11. Current medication and transfusion history;
12. Blood glucose;
13. Amylase;
14. Insulin protocol;
15. Alcohol use (if known);
16. Familial history of diabetes; and
17. HLA A, B, Bw4, Bw6, C, DR and DQB antigens. When reporting DR antigens, DRBI, and DRB3/4/5 must be reported. The lab encourages to report splits for all loci as shown in Appendix 3A.

[...]

5.1.3 Mechanical preservation machine

- Mechanical preservation machines are permitted for transporting an organ.
- The cassette containing the organ must be labeled with the organ type (i.e. left kidney, right kidney), ABO, ABO subtype when used for allocation, and UNOS ID.
- The external surface of a mechanical preservation machine must be labeled with:
 - the standardized external label distributed by the OPTN contractor, or
 - an alternate label that contains all information included on the OPTN contractor standardized label.

- Before re-using a mechanical preservation machine that was used to transport an organ, all labels from the previous donor organ must be removed.

[...]

5.3 EXTERNAL LABELING REQUIREMENTS

When a disposable shipping box or cooler is used to transport a deceased donor organ, the Host OPO must use the standardized external label distributed by the OPTN contractor. When a mechanical preservation machine is used, the OPO or Transplant Center, as applicable, may use an alternative label if the label contains all of the required information.

The external transport container must be labeled with the: UNOS Donor I.D., Donor ABO type, ABO subtype when used for allocation, a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. The label must be securely affixed to the external transport container. The OPTN contractor distributes a standardized external label that includes this information and must be utilized.

[...]

5.4.1 Solid organ

The Host OPO is responsible for ensuring that ~~the~~ a secure label identifying the specific contents (e.g., liver, right kidney, heart) is attached to the outer bag or rigid container housing the donor organ. The OPTN contractor distributes a standardized internal label that must be utilized for this purpose. In addition to the contents of the package, the label information must include the UNOS Donor I.D. ~~and~~ donor ABO type, and ABO subtype when used for allocation.

5.4.2 Tissue typing materials

Each separate specimen container of tissue typing material must have a secure label with two unique identifiers, one being UNOS Donor I.D., and one of the following three: donor date of birth, donor initials or locally assigned unique ID, (donor ABO is not considered a unique identifier). Additionally each specimen should be labeled with Donor ABO, ABO subtype when used for allocation, date and time the sample was procured and the type of tissue. In the preliminary evaluation of a donor, if the UNOS ID or ABO is not available, it is permissible to use a locally assigned unique ID and one other identifier for the transportation of initial screening specimens.

5.4.3 Vessels

The vessels must be labeled with the standardized vessel label distributed by the OPTN contractor. The information must contain the: recovery date, ABO, ABO subtype when used for allocation, all serology results, container contents, and the UNOS Donor ID. If the donor is in a "high risk"¹ group as defined by the

¹ Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. CDC MMWR Recommendations and Reports. 1994;May 20/ 43(RR-8):1-17.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm>

Centers for Disease Control and Prevention (CDC), the label must indicate that the vessels are from a donor who meets the CDC criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state “for use in organ transplantation only.” If packaged separately from the organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container and the standardized vessel label must be affixed to the outermost barrier.

[...]

5.5.1 Documentation accompanying the organ

- Complete donor documentation-must be sent in the container with each transported organ. This documentation must include:
 - ABO typing source documentation;
 - ABO subtyping source documentation when subtype is used for allocation;
 - Infectious disease testing results;
 - Medical/Behavioral History form;
 - Donor Evaluation;
 - Complete record of the donor;
 - Consent form; and
 - Organ quality information as noted in Policy 2.5
- Donor documentation must be placed in a watertight container.
- Donor documentation may be placed in either:
 - a location specifically designed for documentation, or
 - between the outer and inner containers.
- Whenever a deceased donor organ is transported, the Host OPO or the Transplant Center, as applicable, must include in the donor documentation the source documentation.

5.6.1 Verification of labeling and documentation for deceased donor organs or vessels.

When a deceased donor organ or vessel(s) is procured, the Host OPO must ensure the accuracy of the donor’s ABO, and ABO subtype when used for allocation, on the container label and within the donor’s documentation. Each OPO must establish and implement a procedure for verifying the accuracy of organ/vessel packaging labels by an individual other than the person initially performing the labeling and documentation requirements stated in policy 5.3, 5.4 and 5.5. The Host OPO must maintain documentation that such separate verification has taken place and make such documentation available for audit.

5.7 Verification of Information Upon Receipt of an Organ

Upon receipt of a deceased donor organ and prior to implantation, the Transplant Center must determine that it has received the correct organ for the correct transplant candidate by verifying the recorded donor and recipient ABO, ABO subtype when used for allocation, and UNOS Donor ID, as required by Policy 3.1.2. The Transplant Center must maintain documentation that this verification has taken place and make such documentation available for audit.

[...]

5.8.2 Blood for ABO Confirmation

A "red top" tube of blood, specifically for confirmation of ABO and subtype (when used for allocation), must be sent to the receiving OPO or transplant center with each deceased organ and tissue typing material. This tube must be labeled as described in Policy 5.4.2 with the exception that the blood type may not be indicated on the label, and placed within the insulated container. The Host OPO is responsible for ensuring that the tube is appropriately labeled.

[...]

5.10.2 Vessel Storage

The Transplant Center must designate a person to monitor and maintain records, destroy, and notify the OPTN of outcome and/or use of vessels. This designated person must maintain information on all donor vessels including monitoring and maintaining all records relating to the use and management of donor vessels (e.g. subsequent positive serology testing, monitor inventory of stored vascular conduits). This person must monitor the refrigerator, ensure records are up to date and available with the conduits, destroy the vessels when expired, and notify the OPTN of its use or disposal.

- The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).
- The vessels must be stored in a rigid, sterile sealed container labeled with the recovery date, ABO, ABO subtype when used for allocation, serology, container contents, and the UNOS Donor ID for tracking. The standardized vessel label distributed by the OPTN contractor must be attached to the outer sterile barrier bag and information on the label must include all of the above information and all serology testing results. The appropriate packaging of vessels should be completed in the donor operating room. Label should clearly state for use in organ transplantation only.
- The vessel(s) must be stored in a secured refrigerator with a temperature monitor and maintained within a range of 2 - 8 degrees Celsius.
- There must be daily monitoring of the vessel(s) with documented security and temperature checks by the transplant center.
- The vessel(s) can be stored up to a maximum of 14 days from the original recovery date.
- The transplant center must maintain a log of stored vessels.
- The transplant surgeon must have around the clock access to the donor information prior to using the donor vessel(s) in a recipient other than the intended recipient.

[...]

12.3.1 ABO Identification. The member transplant hospital must ABO type, ~~and subtype if appropriate~~, each living donor on two separate occasions prior to the donation. Two separate occasions are defined as two ABO samples taken at different times, and sent to the same or different laboratories.

12.3.2 ABO Subtype Identification. The member transplant hospital subtyping a living donor whose initial subtype test indicates the donor to be non-A₁ (negative for

A₁ (e.g. A₂) or non-A₁B (negative for A₁B (e.g. A₂B)), must complete a confirmatory second determination test prior to donation to assess the accuracy of the result. Blood samples for subtype testing must be taken on two separate occasions, defined as two samples taken at different times and sent to the same or different laboratories. Samples tested must not be taken after a blood transfusion. When the initial and confirmatory second determination subtypings are the same result, the result can be used to determine transplant compatibility with the intended recipient or any other potential recipient (e.g., in a paired exchange program or allocation of non-directed donor). If the results do not indicate the same subtype, the donor must be allocated based on the primary blood type, A or AB.

[...]

- 12.7 Responsibility for Transport of Living Donor Organs.** The following policies address standardized packaging of living donor organs and tissue typing materials to be transported for the purposes of organ transplantation. When an organ from a living donor is procured, the Transplant Center shall be responsible for ensuring the accuracy of the donor's ABO and subtype (when used to determine transplant compatibility) on the container label and within the donor's documentation. The Transplant Center 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 Policies 12.7.1 and 12.7.5. The Transplant Center shall maintain documentation that such separate verification has taken place and make such documentation available for audit.

Upon receipt of an organ from a living donor and prior to implantation, the Transplant Center shall be responsible for determining the accuracy and compatibility of the donor and recipient ABO and subtype (when used to determine transplant compatibility) and document this verification in compliance with Policy 3.1.2.

[...]

- 12.7.2** The Transplant Center is responsible for ensuring that the Donor I.D., Donor ABO type and subtype (when used to determine transplant compatibility), and a secure label identifying the specific contents (e.g., liver segment, right kidney) are attached to the outer bag or rigid container housing the donor organ prior to transport.
- 12.7.3** Each separate specimen container of tissue typing material must have a secure label with the Donor I.D., Donor ABO type and subtyping (when used to determine transplant compatibility), date and time the sample was procured and the type of tissue. The Transplant Center is responsible for labeling the materials appropriately.
- 12.7.4** The Transplant Center is responsible for affixing to the transport container the standardized label completed with the Donor I.D., Donor ABO type and subtyping (when used to determine transplant compatibility), 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.

12.8 Reporting Requirements. Refer to Policy 7.0 (Data Submission Requirements) for the member that is responsible for submitting living donor forms.

12.8.1 All living donors must be registered with the OPTN Contractor via the living donor feedback form prior to surgery.

12.8.1.1 The living donor transplant program must use ~~the~~ source documents from both ~~the~~ an initial and confirmatory second determination ABO typings, and subtypings (when used to determine transplant compatibility), to enter the living donor's ABO data on the Living Donor Feedback Form. Additionally, each living donor program must develop, implement, and comply with a procedure to verify that the living donor's ABO and subtyping was correctly entered on the Living Donor Feedback Form with both the initial and confirmatory second determination ABO typing and subtyping source documents by an individual other than the person initially entering the donor's ABO data. A transplant program must document that each ABO typing and subtyping entry was performed in adherence to the program's protocol. The program must maintain this documentation, and make it available to the OPTN Contractor, upon request.

UNOS Bylaws, Appendix B, Attachment IIA, Section I -

I ABO Blood Group Determination

I1.000 ABO blood group must be performed by techniques compliant with Federal regulations.

I2.000 If testing for the A1 subgroup of ABO group A is performed, the extract of Dolichos biflorus must be used at a dilution and with a technique documented not to agglutinate ~~A2~~ non-A₁ cells. Each assay or batch test run must include known A1 and ~~A2~~ non-A₁ cells as controls.

I3.000 If titration of anti-ABO antibodies is performed, the procedure and criteria for interpretation must be established and validated by the laboratory.

I4.000 Laboratories using molecular techniques for ABO blood grouping must conform to all pertinent standards in Section K- Nucleic Acid Analysis.

3. **Patient Safety Planning Development (PSPD) Subcommittee** - The Committee reviewed the last two editions of the subcommittee's Patient Safety newsletter. The newsletter was developed to assist members with understanding the importance of reporting safety events, to increase awareness of safety in every day practices, and provide best practices for member access. The Committee agreed that the newsletter contained meaningful information for the community and should be continued on a quarterly basis.

The subcommittee reviewed with the Committee proposed enhancements to the Improving Patient Safety electronic reporting system in UNetSM. The proposal would add fields to the electronic reporting system that would provide essential data needed for trending and analysis of safety events. The Committee agreed that this proposal was a good path forward to collect essential data but cautioned that the addition of fields to the system could be construed as additional data entry and "too burdensome" for members. It was discussed that the proposed changes should enhance reporting mechanisms and not hinder reporting by members. The Committee asked UNOS staff to review the fields that were proposed to assess whether these data could be collected elsewhere within the UNOS

database and thus additional fields would not be needed. The subcommittee also discussed the use of nationally accepted patient harm classification systems to allow the reporter to identify patient involvement at the time of reporting the event. Many members of the committee commented that the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) system may be too complicated for the reporting system but could add benefit for UNOS's internal analysis of the event.

4. **Review of Safety Data and Trends** - The Committee discussed data related to errors that were associated with the OPTN's new labeling system that went into effect in January 2011. The current labeling system was piloted in 2010 and made available for member use in September 2010 prior to the enforced requirement of its use. An OPO Committee representative shared with the Committee that there were 17 packaging and labeling errors reported to the OPTN since the implementation of the new system. It was discussed that seven of the 17 were identified as issues related to a second unique identifier required to be added to the labels of tissue typing materials. This issue also identified problems with consistency in documenting a unique identifier that is specific to the OPO, leaving no way to cross-reference the accuracy of the information. The OPO committee is forming a work group that will address the issue. The Committee had no other concerns related to these data since the OPO Committee is addressing the issues identified.

Transportation failure and near miss data provided by the UNOS Organ Center (OC) were reviewed by the Committee for the timeframe August 2010 – July 2011. About one third of kidneys placed annually are placed through the OC. The Committee made the observation that if the number of transportation failures identified by the organ center were extrapolated to the nation, there would have been approximately 90 kidneys lost during the timeframe of this data review. The Committee discussed that there are no national data to identify the number of discards related to transportation failures. A discard code to identify when organs are discarded due to transportation failures was reconsidered. The request for this code was made under the Committee's previous charge. It would allow OPOs to accurately identify in DonorNet[®] when organs were lost due to transportation failures. It was discussed that there are currently about 20 different discard codes but none specifically related to transportation or shipping failures. The Committee agreed that traditionally this issue has been small in number but it may be more important to collect this data with the increase of paired kidney. Appropriate discard codes will be important to understand how many organs are being lost and to investigate the problem in a timely manner. It was agreed that the programming of this discard code would assist the committee in understanding the magnitude of the issue, and then it should be completed to improve the system. The Committee suggested that a work group may need to be developed if data collected identifies a problem.

5. **ABO Verification Process Performed at Donor Hospitals Standardize ABO Verification Form** – A Committee member shared with the Committee a crosswalk of OPTN, Centers for Medicare Services (CMS), Joint Commission, and WHO recommendations for transplantation standards that was developed by their center. The Committee discussed the overlap of regulation between the organizations and issues related to compliance with each. It was discussed that data shared by CMS and the OPTN show that requirements for ABO verification of typing candidates and for verification at recovery and prior to transplant have outlined a continued safety and compliance issue. Members agreed that this crosswalk could be used to begin the development of a standardized checklist or template for documentation of both verification processes. Members agreed that a checklist resource made available to the transplant community would be beneficial. It was also discussed that the checklist should include OPTN, CMS, and Joint Commission minimum requirements for ABO verification with best practices for adhering to the process of verification. The Committee agreed that this project should be submitted to UNOS leadership and the Executive Committee for committee

work approval. Once approved, an *ad hoc* work group should be created with representation from other committees to address to complete the work.

6. **Linking Donor Risk with Organs, Tissues, and Blood** – A presentation was provided to the Committee on proposed work on a project that could link donor risk and human products donated from a living or deceased donor. The presentation centered on the type of donor and recipient information provided to a center when organs are allocated and how information that would suggest donor risk is processed by the center. It was discussed that it is very important that donor information is recorded accurately and transferred to appropriate clinical staff to care for the patient when donor risk is identified. There is currently no way to link or trace a donor to all products allocated. Information shared about the recipient and donor risk variables are provided in a different way center to center; each according to local practice. A standardized coding system, with unique tracking capabilities, would increase effective communication of donor information and create a system of traceability with the donor and all recipients of donor products. An automated bar code labeling system would assist in storage of the important information on the donor and recipient information.

After the presentation, the Committee discussed the need to conduct a feasibility study to assess the impact, benefits, risks and costs associated with the implementation of a system like this. A system like this must be capable of:

- tracking all donor products allocated;
- collect specific information on all recipients; and
- be accessible to all transplant centers and OPOs.

The Committee discussed the increasing interest in biovigilance in the United States (US) as it began to be recognized in October 2009 with the Public Health Service's (PHS) published gap analysis. This analysis identified a lack of unified labeling system for tracking organs and donor risk. In 2011, a request for information was issued from the Department of Health and Human Services (DHHS) regarding a public-private interest in biovigilance. DHHS began an initiative to reduce risk of hepatitis in the US in 2011. Within the initiative were several recommendations regarding organ donation and transplantation. It was also discussed that new recommendations for high risk donors would be proposed in the near future by the US PHS. Members discussed a previously developed prototype with this potential of tracking that was developed by UNOS and the Centers for Disease Control and Prevention (CDC) several years earlier, but the project did not advance due to a lack of funding.

It was also discussed that the World Health Organization (WHO) issued a report in May 2011 that stressed the need to improve safety and efficacy of transplantation, collaborating collection of data related to safety events and to encourage implementation of a globally consistent coding systems for human cells, tissues and organs that will facilitate traceability. Many other countries have already adopted such a system due to organ transfer from country to country, and the US has adopted this system for blood and some cellular products.

The Committee discussed that human error in sharing information could be minimized by a unique identification system that would be connected to each graft. The unique identification could provide critical standardized information, increase the use of computers to capture and store information thereby decreasing transcription errors, and allow audit of traceability effectiveness. Increasingly, collection of information via computer systems has been implemented to enhance safety and efficiency in organ donation and transplantation. The transfer of information among centers by electronic means ensures a greater level of accuracy but can only be effectively achieved with a nationwide standard labeling and tracking system. The Committee discussed one system, ISBT 128,

has been in development since 1989, which is now in use by more than 4,000 facilities in 63 countries. The Committee will request approval to conduct a feasibility study of all systems that are currently in use by other organizations. If approved, the Committee would collaborate with other OPTN committees and regulatory agencies to develop a system that will work best for organ transplantation and information tracking.

7. **Effective Screening Update** - The Committee reviewed results from an educational initiative undertaken by the Effective Screening Work Group (ESWG) in which outlier kidney programs within expanded criteria donor (ECD) kidney import data reviewed by the group were provided targeted data and a survey to collect information regarding philosophy on setting organ-acceptance criteria. As part of this initiative, letters with data were also provided to 19 kidney programs that appeared to be outliers in the data for acceptance of ECD kidneys when compared with the centers' donor and candidate selection criteria entered into UNetSM. A summary of all survey responses received were reviewed with the committee (**Exhibit C**). The responses show that many centers believe they could do a better job in using organ acceptance criteria within the system. Many offered insights on obstacles to the effective use of screening criteria, such as:

- Concerns of donor information changing after the offer;
- Desire to evaluate every offer;
- Confusion between the Kidney Minimum Acceptance Criteria (Kidney MAC) and other acceptance criteria; and
- Time required for setting criteria on each candidate.

The Committee also reviewed respondents' suggestions for future system enhancements related to screening and additional education requested to be provided on Donation Service Area (DSA) reports and the Report of Organs Offered and Transplanted (ROOT). In summer 2010, the Committee offered an educational newsletter and webinar to assist members with the tools available to assist them with setting screening criteria. The ESWG plans to review data in December 2011 (i.e. such as match run lengths) related to the outlier kidney programs surveyed, to assess the impact of the educational initiatives provided.

A member of the Committee shared that his center's kidney program was one of the programs receiving the outlier data and survey. Based on the data provided, the center lowered its donor acceptance age for import ECD kidneys from 65 to 60 and decreased the number of ECD import kidney offers by 20 percent. The member noted that the transplant administrator for his program and the coordinators that take on-call organ offers were very happy with this result in terms of time or spent working on offers in which the organs will not be used at their center.

The Committee discussed that the current discard rate of import ECD organs is approximately 40 to 45 percent. A balance must be reached between increased screening to decreased the number of offers to place marginal organs with centers that will transplant them and the decision to transplant marginal organs within transplanting centers.

In October 2011 the ESWG plans to send out letters to approximately 20 outlier liver programs to assess their screening philosophies. It was discussed that this project was not approved to continue in 2012, but any data collected via liver letters and surveys will be provided for the Liver and Intestinal Organ Transplantation Committee's Liver Utilization Group to review.

8. **Public Comment Review** – The Committee considered current proposed policies, which were to be released for public comment on September 16, 2011. The Committee’s opinion is shown below for the selected proposals considered within its purview:

- Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors (Living Donor Committee) – The Committee offered the following comments:
 - Making the informed consent process more standardized will be beneficial to all those involved in living donation, not just for the consent process, but also in the education of the donor and recipient.
 - There is a lot of ambiguity in the term “independent” used for the independent donor advocate required for living donor programs. This term needs to be changed, defined, or further clarified.

The Committee voted in support of the proposal: 18 For, 0 Against, 1 Abstention.

- Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors (Living Donor Committee) - The Committee offered the following comments:
 - Deceased donors and their potential recipient(s) are currently afforded safety measures within the process of evaluation that are not available for living donors. It’s important to make living donation an even safer process for the donor and recipient, and to ensure that both individuals continue to do well after donation and transplant.
 - The follow up of a living donor should be discussed during evaluation. For those donors that do not have insurance, many centers bear the burden of the costs of follow up. It should be explained to the donor what type of follow up the transplant center will pay for when insurance is not an option or does not pay.
 - The consent process is vital to living donation process. It is important not only for the health and well being of the donor and recipient, but also to ensure that follow up takes place as required.
 - Include non-melanoma type skin cancers to exclusion criteria.
 - Consider whether BMI is most appropriate indicator for evaluation, should there be a note about
 - Address the timeline between infectious disease testing of the donor and transplant of organ. Suggest within acceptable timeframe of NAT testing.

The Committee voted in support of the proposal: 17 For, 1 Against, 1 Abstention.

- Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up (Living Donor Committee) - The Committee offered the following comments:
 - Prescribed follow up at present is at six, 12, and 24 months. Medicare pays for follow up at 3 months. Should there be flexibility in the first year’s requirements if the center has completed the 3 month follow up (paid by Medicare) and not required to complete the 12 month follow up?
 - The Committee supports this proposal as a safety initiative. It needs to be clear that living donor centers must provide during the evaluation period information that clearly outlines the requirements for follow up and how the follow up information can be obtained, whether in person, via telephone, or with another provide close to the donor’s area of residence.

- The monitoring and evaluation plan needs to clearly identify the type of documentation required to show compliance with donor follow up (i.e. the documentation required for even attempts to contact the donors or their providers to get follow up information).
- The Living Donor Committee could consider a statement on the guidance for follow up that addresses issues related to HIPAA (i.e. do not contact the recipient to obtain information about the donor, that could be a violation of the donor's privacy).
- It should also be considered that living donor centers that are top performing centers for follow up may have resources to obtain follow up that other centers do not have. Many academic centers have endowments that assist them with these types of efforts and ensure their success. The smaller the living donor center the more burdensome follow up requirements may become.

The Committee voted in support of the proposal: 17 For, 1 Against, 1 Abstentions.

- Proposal to Eliminate the Use of an “Alternate” Label when Transporting Organs on Mechanical Preservation Machines and to Require the OPTN Distributed Standardized Label (OPO Committee) - The Committee offered the following comments:
 - The proposal refers to the external labeling of the perfusion device. Many OPOs use a pump where an internal label is attached to the internal cassette and then an external label is attached to the outside of the pump. Consider internal and external labeling requirements with standardized labels.
 - In some pumps, the lids can be changed during the transport process. Suggest not including policy language that requires the label be to a section of the pump that may be removed or changed in transport.
 - Consider clarifying the term “transport” to include any time the organ leaves the recovery room, or whether it means any time the organ leaves the recovery facility.

The Committee voted in support of the proposal: 19 For, 0 Against, 0 Abstentions.

9. **Future Meeting Date** – The full Committee will next meet face-to-face on April 4, 2012, at O’Hare Hilton Hotel, Chicago, Illinois.

OPTN/UNOS OPERATIONS COMMITTEE MEETING ATTENDANCE

Name	Position	Chicago, Illinois September 15, 2011
Phillip C. Camp, Jr., MD	Committee Chair	x
Jean Davis	Committee Vice Chair	x
Sharon Bartley, MS, RN	Region 1 Representative	x
Alden Doyle, MD, MPH & TM	Region 2 Representative	x
Michael Angelis, MD	Region 3 Representative	x
Dean Henderson, MHA, BSMT, CHT	Region 4 Representative	x
P.J. Geraghty, MBA, CPTC	Region 5 Representative	x
Kathy Jo Freeman, RN, MSN	Region 6 Representative	x
Glen Geditz	Region 7 Representative	x
Zoe Stewart, MD, PhD	Region 8 Representative	By Phone
Theresa M. Daly, MS, FNCP	Region 9 Representative	x
Andrea Martinovich, RN, BSN	Region 10 Representative	
Jerita Payne, APRN, BC	Region 11 Representative	x
Karen R. Cox, PhD, RN	At Large Representative	x
Sharon Alcorn, RN, BSN, CCTC	At Large Representative	x
Daniela P. Ladner, MD	At Large Representative	x
J.T. Rhodes, CPA	At Large Representative	x
Kristin Delli Carpini, MPH	At Large Representative	x
Julia Hart, BS	At Large Representative	By Phone
Linda Ohler, RN, MSN, CCTC, FAAN	At Large Representative	x
Darla Phillips, RN, MSN	At Large Representative	x
Helen (Gigi) Spicer, RN, BSN	At Large Representative	x
Michael Hagan, DO, MHSA, CMQ	Visiting BOD Member	x
Raja Kandaswamy, MD	SRTR	x
Raelene Skerda	SRTR	x
Robert W. Walsh	Ex Officio/HRSA	x

UNOS staff attending:

Franki Chabalewski, MSN, RN, Assistant Director, Professional Services Department
 Brian Shepard, Director, UNOS Policy Department
 Darren Stewart, Biostatistician, UNOS Research Department
 Kimberly Taylor, RN, Patient Safety Specialist, Committee Liaison
 Rich Endert, UNOS Tech Support