

5.0 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS

The purpose of Policy 5.0 and its subsections is to:

- state requirements for packaging and labeling organs, tissue typing specimens, and vessels to prevent wastage (and/or to promote safe and efficient use);
- define terms and responsibilities related to packaging, labeling, and transporting organs, tissue typing specimens, and vessels; and
- state requirements for recovering, storing, and using vessels in solid organ recipients.

The responsibility for packaging and labeling deceased donor organs is assigned to the Host OPO. Transplant Center staff may not leave the operating room without allowing the OPO to package and label the organ in accordance with OPTN policy. The OPO must submit a report through the Patient Safety System when a Transplant Center fails to comply with this policy. The OPO will make all reasonable efforts to package and label the organ in a timely fashion. If an organ is repackaged by a transplant center for transport, the Transplant Center will package, label and ship the organ in accordance with this policy and immediately notify the recovering OPO of the repackaging.

5.1 EXTERNAL PACKAGING SPECIFICATIONS

An external transport container is defined as a: disposable shipping box, cooler or mechanical preservation machine. The transplant center or OPO must use both internal and external transport containers to package a deceased donor organ that travels outside the recovery facility.

5.1.1 Disposable shipping box

- If organs, vessels and/or tissue typing materials are shipped commercially, a disposable shipping box must be used.
- The disposable shipping box must be labeled with the standardized label distributed by the OPTN contractor.
- Disposable boxes must not be reused.
- The outer box must be a corrugated plastic or corrugated cardboard that is coated with a water resistant substance with at least 200 pound burst strength.
- The inner container must be a 1.5 inches thick, insulated container OR have an equivalent "R" value.
- A closed colored opaque plastic bag must be placed between the outer container and the insulated container. Closed is defined as being secured in a manner to prevent leakage (i.e. watertight).
- A second closed plastic liner must also be placed inside the insulated container to encase the ice. Closed is defined as being secured in a manner to prevent leakage (i.e. water tight).

5.1.2 Cooler

- Coolers are permitted for non-commercial transporting of organs when the organ recovery team is transporting the donor organ with them from the donor hospital to the candidate transplant center.
- Coolers must be labeled with the standardized label distributed by the OPTN contractor.
- Coolers may be reused if properly cleaned and sanitized.
- Before re-using a cooler, all labels from the previous donor organ must be removed.

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.

5.2 INTERNAL PACKAGING SPECIFICATIONS

All organs that have been packaged on the donor's back table must be handled using universal precautions. The packaged organs from the donor's surgical back table are to be placed directly into the wet iced shipping container. Proper insulation and temperature controlled packaging including adequate ice or refrigeration must be used to protect the organs during transport.

- Organs must be protected by a triple sterile barrier.
- Kidneys and pancreata must be placed in a rigid container, which, if sterile, can be one layer of the triple sterile barrier.
- Hearts, livers, lungs, and intestines do not require a rigid container.
- Vessels must be protected by a triple sterile barrier; if packaged separately from the organ, one barrier must be a rigid container.

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 INTERNAL LABELING REQUIREMENTS

5.4.1 Solid organ

The Host OPO is responsible for ensuring that 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., donor ABO type, 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

Both the vessel container and outer sterile barrier must be labeled with the standardized vessel labels distributed by the OPTN contractor. The information must contain the: recovery date, ABO, ABO subtype when used for allocation, all infectious disease testing

results, container contents, and the UNOS Donor ID. If the donor is in a “high risk”¹ group as defined by the US Public Health Service (PHS) guidance¹, the label must indicate that the vessels are from a donor who meets the PHS 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 and container.

5.5 DOCUMENTATION ACCOMPANYING THE ORGAN OR VESSEL

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 subtype when 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.

5.5.2 Documentation accompanying the vessel

If the vessels are not shipped in the same package as the organ, the same complete donor documentation, as described in Policy 2.5.6.1, must be included with the vessels.

5.6 VERIFICATION OF LABELING AND DOCUMENTATION INCLUDED WITH ORGANS OR VESSELS

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 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.

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>

5.8 MATERIALS FOR TISSUE TYPING AND ABO CONFIRMATION

5.8.1 Policy for tissue typing specimen, medium, and shipping requirements

Each OPO must have a written policy established with an OPTN member laboratory(s). The policy shall include specific descriptions of the type of specimen, and medium, in addition to the shipping requirements of same.

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.

5.8.3 Typing material for each kidney and pancreas

In view of the frequent need for regional shipment of pancreas and kidney allografts, sufficient specimens for several crossmatches are required. However, minimal typing material to be obtained for EACH kidney and pancreas will include the following:

- 2 ACD (yellow top) tubes
- 3 to 5 lymph nodes
- One 2 X 4 cm. wedge of spleen in culture medium, if available

5.8.4 Typing material for all other organs

- The Host OPO will provide specimens for tissue typing if requested.

5.9 DECEASED DONOR ORGANS THAT REMAIN IN THE SAME OPERATING ROOM SUITE AS THE INTENDED CANDIDATE(S)

5.9.1 When deceased donor organs are recovered and 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 to ensure identification of the correct donor organ for the correct recipient. A "time out" prior to leaving the donor operating room and an additional "time out" upon arrival in the candidate operating room are required. These "time outs" are for the Transplant Center to confirm and document that the correct organ was identified for the correct candidate prior to transplant (refer to Policy 3.1.2).

5.10 VESSEL RECOVERY, TRANSPLANT, AND STORAGE

The intent of this policy is to permit:

- vessel recovery and immediate use in a solid organ transplant (for example either a current liver or pancreas transplant); and
- vessel recovery and storage for use in a subsequent solid organ transplant from a donor with a different UNOS Donor ID (for example, when the vessel(s) and the liver or pancreas allograft are being transplanted from different donors with different numbers).

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.
- 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 and must be protected by a triple sterile barrier, one of which must be the rigid container. labeled with the recovery date, ABO, ABO subtype when used for allocation, infectious disease results container contents, and the UNOS Donor ID for tracking. The standardized vessel label distributed by the OPTN contractor must be affixed to the outer most sterile barrier bag and information on the label must include recovery date, ABO, all infectious disease results, container contents, and the UNOS Donor ID. If the donor is in a “high risk”¹ group as defined by the US Public Health Service (PHS) guidance¹, the label must indicate that the vessels are from a donor who meets the (PHS) 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 removed from the triple sterile barrier, the transplant center must re-label the vessels prior to storage.
- 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.

5.11 TRANSPORTATION RESPONSIBILITY

The purpose of this policy is to define the responsibility of transportation costs for deceased donor organs.

5.11.1 Renal organs

The Host OPO is responsible for transportation costs for deceased donor kidney(s) and associated tissue typing material pursuant to CMS regulations.

5.11.2 Non-renal organs

The member that accepted the organ is responsible for transportation costs for deceased donor non-renal organ(s) (to include kidney-pancreas and pancreas islet) and associated tissue typing material to its destination. If a donor organ is first accepted by one member and subsequently forwarded to another member, payment of transportation costs for

forwarding the organ is the responsibility of the member that finally accepts the organ, unless otherwise agreed upon by the parties involved. If a non-renal organ has been accepted and transported, but cannot be used for transplantation, the member that finally accepted the organ is responsible for payment of transportation costs, unless otherwise agreed upon by the parties involved. The OPTN contractor will not incur transportation costs for non-renal organs or tissue typing material.

5.11.3 Tissue typing material

The Host OPO is responsible for payment of transportation costs for tissue typing material sent to crossmatch potential recipients of a deceased donor kidney. The member that requested the tissue typing material is responsible for the payment of transportation costs for the tissue typing material sent to crossmatch potential recipients for a non-renal organ.