At-a-Glance

- **Proposal to Standardize Label Requirements for Vessel Storage and Vessel Transport**

- **Affected/Proposed Policy:** Policy 5.0 – Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials

- **Organ Procurement Organization (OPO) Committee**

  This proposed change makes the labeling requirements for vessel storage consistent with those for vessel transport. Recent Policy 5.0 changes eliminated the requirement that a label be placed directly on the vessel container for transport and require that the vessel label distributed by the OPTN contractor be attached to the outer barrier of the triple sterile barrier. Policy 5.10.2, currently requires the labeling of the vessel container when vessels are stored and requires the OPO to complete the labeling in the donor OR. As such, there is an inconsistency in vessel labeling requirements. This proposed policy modification will not affect the labeling requirements for vessel transport, and will clarify that containers for vessel storage do not require the vessel container itself to be labeled. The vessels must be placed in a triple sterile barrier, one of which is the rigid container, and labeled with the OPTN distributed label.

- **Affected Groups**
  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Physicians/Surgeons
  Transplant Program Directors

- **Number of Potential Candidates Affected**
  This change would affect all candidates that require a previously stored vessel.

- **Compliance with OPTN Strategic Goals and Final Rule**
  The HHS Program Goals affected by the proposal include:
  - Patient Safety – Information provided on the labels will have a consistent format.
  - Maximum Capacity – fewer labeling errors mean fewer discarded vessels.
  - Operational Effectiveness - by requiring the vessel label to be placed on the outmost of three sterile barriers, and not on the container itself, the process best supports patient safety functions by not allowing the container to be stored without the barriers.

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Organ Procurement Organization (OPO) Committee

Summary and Goals of the Proposal:

This proposed change makes the labeling requirements for vessel storage consistent with those for vessel transport. Recent Policy 5.0 changes eliminated the requirement that a label be placed directly on the vessel container for transport and require that the vessel label distributed by the OPTN contractor be attached to the outer barrier of the triple sterile barrier. Policy 5.10.2, currently requires the labeling of the vessel container when vessels are stored and requires the OPO to complete the labeling in the donor OR. As such, there is an inconsistency in vessel labeling requirements. This proposed policy modification will not affect the labeling requirements for vessel transport, and will clarify that containers for vessel storage do not require the vessel container itself to be labeled. The vessels must be placed in a triple sterile barrier, one of which is the rigid container, and labeled with the OPTN distributed label.

Background and Significance of the Proposal:

This issue regarding the inconsistency in labeling the vessel container for transport and storage was brought to the Committee's attention by an OPTN member and the UNOS Regional Administration. Recent policy changes only require that the vessel label distributed by the OPTN contractor be placed on the outside of the triple sterile barrier surrounding the vessel container when a vessel is transported. The changes do not require the vessel container itself to be labeled. However, policy further states that when a vessel is stored, the vessel container must be labeled and then stored in a triple sterile barrier with the OPTN contractor's labels placed on the outmost barrier. Policy also assigns responsibility to the OPO to complete all packaging and labeling in the donor operating room. Because of the resulting confusion, the Committee agrees that clarification is necessary.

Recently, the Committee implemented a new labeling system that has been well received by members. Members recognize the importance of a consistent and standardized packaging and labeling practice. As such, the Committee agreed that since vessels must be stored in a rigid container as part of a triple sterile barrier that the vessel container itself does not require a label, but that the label provided by the OPTN contractor should be used on the outmost barrier. This effectively eliminates the need for a vessel container label and would be consistent with the current labeling requirements for transporting vessels.

- ***Strengths and weaknesses:*** The strength of this proposal is that it provides needed consistency in vessel labeling for both transport and storage of vessels. It also eliminates the possibility of centers storing vessels in just the containers (which has been reported). This practice poses a significant risk to patient safety, as the vessel is not protected by a triple sterile barrier. One weakness is that transplant centers will have to modify their practice and protocols if they are currently not storing vessels in the triple sterile barrier and will require some staff education.

- ***Description of intended and unintended consequences:*** This proposed change will require transplant centers to package and label stored vessels in the same manner that they are packaged and labeled for transport. As such, transplant centers may need to modify their procedures for the storage of vessels. The intended consequence is that all vessels are labeled the same when transported or stored. An unintended consequence is that vessels may be wasted if transplant centers remove the outer sterile barriers for storage and do not label them properly.

  The Committee will request data from the Department of Evaluation of Quality (DEQ) beginning six months after implementation and every six months after that to assess the effectiveness of this policy change in safeguarding vessels that are stored.

Supporting Evidence and/or Modeling:

This proposed change will make policy language regarding packaging and labeling of vessels for storage consistent with required labeling practices of vessels for transport. The Committee comprises experts in packaging and labeling of organs.

Expected Impact on Living Donors or Living Donation:

Although this policy change has no current impact on living donors, it is important to note that the Living Donor Committee is currently proposing changes to Policy 12.0 that will make the packaging and labeling of living donor organs consistent with those of deceased donor organs. This proposed change, if approved, will effectively make the two policies different and require further consideration.

Expected Impact on Specific Patient Populations:

No known specific impact to candidates other than to improve safety when storing vessels for potential recipients and to possibly eliminate vessels being discarded due to errors in packaging and labeling.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The HHS Program Goals affected by the proposal include:

- Patient Safety – through consistent packaging and labeling of vessels for storage, information transferred on the labels will have a consistent format and vessels will be packaged for storage in a consistent way.
- Maximum Capacity – fewer packaging and labeling errors can result in fewer discarded vessels.
- Operational Effectiveness - by standardizing the vessel packaging and labeling, the process for will make improvements that best support critical network functions.

Plan for Evaluating the Proposal:

Once the policy is implemented, every six months the Committee will review a list of all vessel labeling and packaging errors that have been reported and determine if the standardized packaging and labeling has decreased the number of errors. They will ask the questions:

- Has there been a decrease in the number of labeling errors since the vessel container labeling has been standardized?
- Can we attribute any of the errors to the new labeling requirements?

OPOs and transplant centers will be expected to comply with this policy. The DEQ will evaluate member compliance with this policy.

- ***Policy Performance Measures:*** Data collected from DEQ that lists the types of errors made in labeling will be reviewed.

Additional Data Collection:

No additional data collection is necessary.

Expected Implementation Plan:

OPOs and transplant center staff who package vessels for transport or storage must review the policy, understand the correct labeling and packaging procedure, and train staff to comply with this change. OPOs and transplant centers can choose to place a label directly on the vessel container, but it is not required. However, transplant centers must store vessels in the triple sterile barrier that has a completed OPTN vessel label affixed to the outmost barrier.

This policy will be effective 30 days after the transplant community receives notification of the OPTN/UNOS Board of Director's approval of the policy.

This proposal will not require programming in UNET^{SM}.

Communication and Education Plan:

Because the proposed policy change does not involve changes to UNet^{SM} and only requires OPOs to modify their behavior, we will likely not be distributing system notices, but we will use all other standard educational methods such as policy notices, short UNOS Update articles, and short articles in the e-newsletter and member archives. Additionally, no training webinars or live meetings will be necessary.

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice	Appropriate staff from OPOs and transplant centers	Policy notice within e-newsletter	30 days after approval at board meeting
Article in e-newsletter in the policy-related category	Target appropriate staff at OPOs and transplant centers in headline.	e-newsletter and accessing URL of member archive	Earliest monthly issue after policy change is approved.

Monitoring and Evaluation:

During on-site reviews at OPOs, the Department of Evaluation and Quality (DEQ) site surveyors will evaluate compliance with this policy through
interviews, observations, and obtaining copies of the following:

- The consent form used by the OPO that must include language indicating that vessels will be used for transplant; and

- The packaging label to verify that it contains the recovery date, ABO, serology, container contents and the Donor ID number indicating if the donor is CDC high risk. In addition, the label should clearly state "for use in organ transplant only."

During on-site reviews at transplant centers, site surveyors will interview the designated staff who monitor and maintain the extra vessels and obtain a copy of the center's policy and procedure for handing vessels. The vessel monitoring log will be reviewed to verify the following:

- Vessels are stored for a maximum of 14 days from their original recovery date; and • Documentation that daily monitoring of vessels including, documented security checks, and recorded daily temperature checks (note: policy requires vessels to be stored between 2 and 8 degrees Celsius).

DEQ staff will request a corrective action plan if the OPO or transplant center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Policy or Bylaw Proposal:

5.0 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS [NO CHANGE]

5.1- 5.3 [No Change]

5.4 INTERNAL LABELING REQUIREMENTS

5.4.1 – 5.4.2 [No Change]

5.4.3 Vessels [No Change]

The vessels must be labeled with the standardized vessel label distributed by the OPTN contractor. The information must contain the: recovery date, ABO, all serology results, container contents, and the UNOS Donor ID. If the donor is in a "high risk"[1] group as defined by the 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 – 5.9 [No Change]

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 [No Change]

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 and must be protected by a triple sterile barrier, one of which can be the rigid container. ~~labeled with the recovery date, ABO, serology, container contents, and the UNOS Donor ID for tracking.~~ The standardized vessel label distributed by the OPTN contractor must be ~~attached~~affixed to the outermost sterile barrier bag and information on the label must include ~~all of the above information and all serology testing results~~the: recovery date, ABO, all serology results, container contents, and the UNOS Donor ID. If the donor is in a "high risk"[1] group as defined by the 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 ~~L~~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.

5.11 TRANSPORTATION RESPONSIBILITY [No Change]