At-a-Glance

- **Proposal to Eliminate the Use of an "Alternate" Label when Transporting Organs on Mechanical Preservation Machines and to Require the OPTN Distributed Standardized Label.**

- **Affected/Proposed Policy:** 5.1.3 Mechanical Preservation Machine and 5.3 External Labeling Requirements.

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

  Current policy allows the use of an alternate label when OPOs transport an organ on a perfusion machine. OPOs create their own type of labels resulting in inconsistent labeling. The proposed policy changes eliminate the use of alternate shipping labels on mechanical preservation machines and require OPOs to use a new standardized label that is part of the current color-coded labeling system distributed by the OPTN Contractor. This change would make labels for perfusion machines consistent with the labels used for all deceased and living donor organs that are transported outside of donor hospitals.

- **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
  Organ Candidates

- **Number of Potential Candidates Affected**
  There are approximately 2,779 deceased donor organs recovered and transported on mechanical preservation machines each year for candidates. Consistent and standardized labeling of these organs will improve patient safety and potentially lower the number of organs lost during the shipping process.

- **Compliance with OPTN Strategic Goals and Final Rule**
  This proposed change complies with the OPTN strategic goal of improving patient safety since it makes labels for perfusion machines consistent with other labeling practices.

- **Specific Requests for Comment**
  The Committee would like to know if this change would have a major impact on the packaging and labeling processes of OPOs and transplant centers.

Proposal to Eliminate the Use of an "Alternate" Label when Transporting Organs on Mechanical Preservation Machines and to Require the OPTN Distributed Standardized Label.

Affected/Proposed Policy: 5.1.3 Mechanical Preservation Machine and 5.3 External Labeling Requirements.

Organ Procurement Organization (OPO) Committee

Summary and Goals of the Proposal:

Current policy allows the use of an alternate label when OPOs transport an organ on a perfusion machine. OPOs create their own type of labels resulting in inconsistent labeling. The proposed policy changes eliminate the use of alternate shipping labels on mechanical preservation machines and require OPOs to use a new standardized label that is part of the current color-coded labeling system distributed by the OPTN Contractor. This change would make labels for perfusion machines consistent with the labels used for all deceased and living donor organs that are transported outside of donor hospitals.

Background and Significance of the Proposal:

At the Living Donor Committee's request, the OPO Committee considered the language of Policy 5.1.3 (Mechanical Preservation Machine) that allows OPOs to use an alternate label when shipping or transporting deceased donor organs that are on mechanical preservation machines. Policy 5.3 (External Labeling Requirements) provides similar language, which allows OPOs to use of an alternate label. In contrast, the Living Donor Committee's proposed policy changes would require OPOs and transplant centers to use the label distributed by the OPTN Contractor when shipping and transporting living donor organs.

Currently, many OPOs and transplant centers develop their own labels to place on preservation machines when shipping or transporting organs. They do this primarily because the label the OPTN Contractor distributes is too big for the machine and/or the adhesive often sticks to the expensive machine making it difficult, if not impossible, to remove. Because each OPO creates their own label, there is no consistency in how the machines are labeled for transport.

The OPO Committee implemented a new labeling system in January 2010 with the goal of making all organ transport labels consistent throughout the country. The Committee agreed that using an alternate label conflicted with this goal and could create a patient safety concern since OPTN members might not be familiar with each label and could complete them differently. The labels distributed by the OPTN Contractor are required by policy and, when properly completed, contain all of the required information about any given organ type. A new label will be developed for preservation machines that is consistent with the current OPTN color-coded labeling system. This label will be required by policy.

The Committee unanimously recommended striking the language in Policy 5.0 that permits the use of an alternate label. This edit would make all labeling consistent. The Committee also recommended the development of two different-sized labels that would fit on or in a sleeve that would attach to the two types of preservation machines currently in use today.

Collaboration:

The OPO Committee collaborated with the Living Donor Committee to make labeling consistent when transporting or shipping both deceased and living donor organs.

Alternatives considered:

The Committee considered allowing OPOs and transplant centers to continue using alternate labels but agreed that label consistency was critical when trying to reduce errors.

Strengths and weaknesses:

This proposed change resolves any issues created by inconsistent practices in labeling organs, regardless of the type of shipping container (i.e. box, cooler or preservation machine). The committee did not identify any weaknesses.

This proposal does not require additional data collection and should not be a financial burden to the community since OPOs and transplant centers already have to purchase labels from UNOS, or are producing their own preservation machine labels locally.

Description of intended and unintended consequences:

The intended consequence of the proposed policy change is that all organs will be labeled and color coded consistently, regardless of the type of container used in transport (box, cooler or mechanical preservation machine). We anticipate that this change will eliminate errors because of the consistency in labeling as opposed to each OPO and transplant center making its own. OPO and transplant center staff will be more familiar with these labels and, when completed properly, they will contain all of the information required by policy. The impact is improved patient safety through a reduction in labeling errors, and a decrease in the number of lost organs during currier transport.

The committee does not envision any unintended consequences.

Supporting Evidence and/or Modeling:

OPTN data show that in 2010, 4,449 kidneys were placed on perfusion machines at an OPO or transplant center. Out of these, 2,779 were transported on the machines to a different location (i.e. OPO to transplant center). From January 2011 to June 2011, one out of 17 reported packaging and labeling errors occurred due to inaccurate labeling of a perfusion machine. Consistency and standardized labeling of these machines will enhance patient safety for these candidates.

Expected Impact on Living Donors or Living Donation

Not applicable. This policy makes deceased donor policy consistent with that of living donor policy.

Expected Impact on Specific Patient Populations

Although there is no known impact on specific patient populations, consistent labeling should result in a safer environment for those candidates that receive organs that are transported on a pump.

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

The proposed changes meet the program goals of Patient Safety and Maximum Capacity. By making labeling practices consistent, organs will be labeled with appropriate and complete information, which will eliminate or reduce the chance of error. Patients will receive appropriately labeled organs and the number of organs that were wasted because of improperly labeled organs or the use of alternate labels will be reduced.

Plan for Evaluating the Proposal:

- ***What questions or hypotheses are guiding the evaluation of the proposal?***
  - Has the use of a standardized label reduced the number of errors when a mechanical preservation machine has been used in the transport of organs?

- ***Policy Performance Measures:***
  - The Committee will evaluate data that is self-reported to the Department of Evaluation and Quality regarding packaging and labeling errors.

- ***Time Line for Evaluation:***
  - Once the change is implemented, the Committee will evaluate packaging and labeling errors every 6 months.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

UNOS will create two different-sized labels that will fit on both of the preservation machines currently used by transplant professionals. Members can order these labels from the UNOS on-line store. OPTN members will need to familiarize themselves with the new labels and this policy change, complete the labels and apply them to the preservation machine.

This proposal will not require programming in UNet^{Sm}.

Communication and Education Plan:

Last year, we introduced the transplant community to the new color-coded labeling system provided by the OPTN. We communicated the availability of these labels as well as how OPOs should use them when shipping organs. We will use similar communication methods to promote the new label required when shipping organs on a preservation machine. The new label will be an addition to the already existing label system and members will be able to access them the same way they access their current shipping labels. Therefore, our communication plan will focus on the addition to the currently existing label system and that members are required by policy to use this new label (instead of their own alternate version).

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 archive. We should also work with AOPO and NATCO to see if they can promote the newly required shipping labels in their own communication resources, such as their websites and their e-newsletters.

UNOS provided members with a live meeting training when introducing the color-coded labeling system. If UNOS repeats this training, it will add information about the use of the new label that would accompany organs shipped with a preservation machine.

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Standard policy notice	OPOs and transplant centers with living donor programs.	e-newsletter with a link to the policy notice on the member archive.	30 days after the board meeting where the policy proposal was approved.
UNOS Update Article	Same as above	Magazine	After the policy proposal is approved by the board but before the community is required to use the labels.
E-newsletter articles	Same as above	Email/member archive	Several mentions beginning at least three months before OPOs and transplant centers are required to implement the policy change.

Education/Training Activities			
Education/Training Description	**Audience(s)**	**Deliver Method(s)**	**Timeframe and Frequency**
A live meeting training on how to access and use the organ shipping labels, including the new label for organs shipped with preservation machines.	Same as above	Live Meeting/Webinar	Ideally, two trainings offered on different days at alternate times and at least 30 days before the policy is implemented.

Monitoring and Evaluation:

The UNOS Department of Evaluation and Quality will continue to review and verify an OPO's external packaging supplies during onsite reviews.

Policy or Bylaw Proposal:

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

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 of the ~~recovery~~ facility where the organ is recovered.

5.1.1 – 5.1.2 [No Change]

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, and UNOS ID.
- The external surface of a mechanical preservation machine must be labeled with~~:~~
  - ~~o~~ the standardized external label distributed by the OPTN contractor~~, or~~
  - ~~o 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 [No Change]

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.~~

5.4 INTERNAL LABELING REQUIREMENTS—5.11 TRANSPORTATION RESPONSIBILITY [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. and donor ABO type.

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, 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, 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.