Labeling and Packaging of Organs & Vessels

Training Session

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Labeling Subcommittee Co-Chairs
Questions to Run On

- What impact will the new labeling system have on my OPOs processes?

- What will I have to do to make sure that we are compliant with OPTN policy and that our staff is adequately trained?
Objectives

- The presenters will:
  - Explain the background of the project.
  - Describe the new label system and how to use it.
  - Identify policy implications when using the new labels.
  - Review labeling methods for various scenarios (i.e. enbloc, multi-visceral)
  - Consider the benefits of the new resource verification form.
Currently OPOs/transplant centers are required to use the external labels provided by the OPTN contractor (UNOS)

Early 2008, the OPTN introduced a labeling system (included internal label NOT required by policy...confusion)

Since that time there has been an increase in reported labeling errors

Numerous comments from the community regarding concerns about the new system
Action Plan

- OPO Committee formed a Subcommitee that evaluated the current labeling system, developed the new system, and sought full committee and other committees' support

- Pilot Study conducted Jan – March 2010.
  - 5 OPOs (varying size/geography)
  - Utilized the new system for two months
  - Changes made based on pilot site recommendations
  - Final approval by OPO Committee
New System

- External AND Internal label for each organ
- **Internal label is not required** by policy until Board review and approval in November 2010 (but is available with the entire system)
- Each organ has its own assigned color for both internal and external labels
- No place for verification signatures (not required by policy)
  - Each OPO is still required to retain documentation of the verification of accurate labeling (Policy 5.6.1.)
  - Verification Form was pilot tested and is available for use to fulfill above policy should an OPO wish to use it
Labeling System

External Labels
8 ½ X 10 ½

Matching Internal Labels
4 ½ X 7 ½

OPTN
LIVER

DONATED
HUMAN ORGAN/TISSUE
for TRANSPLANT

TO (INSTITUTION):

CITY: STATE: TEL: ( ) -

If available,
PRIMARY FLIGHT #: CONNECTING FLIGHT #:

In case of delays or problems call UNOS Organ Center at 1-800-292-9537 a 24 hour number.

This shipment is made possible by an exchange of information through United Network for Organ Sharing, a charitable, non-profit organization which has no proprietary interest in this container or its contents.

HANDLE WITH CARE

BIOLOGICAL PRODUCTS—NOT RESTRICTED, PACKED IN COMPLIANCE WITH IATA PACKAGING INSTRUCTION 650 (WET ICE).
LIVER

UNOS ID

DONOR ABO

BIOHAZARD
Verification for Accuracy of Documentation and Packaging of Transplantable Organs

Verification of an accurate donor label and appropriate documentation accompanying each transplantable organ.

UNOS ID: [Box] DONOR ABO: [Box]

Check all that apply: (Verification by two individuals is required; one of whom must be an OPO staff member)

<table>
<thead>
<tr>
<th></th>
<th>Right Kidney</th>
<th>Left Kidney</th>
<th>Pancreas</th>
<th>Liver</th>
<th>Heart</th>
<th>Right Lung</th>
<th>Left Lung</th>
<th>Intestine</th>
<th>Other</th>
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<tbody>
<tr>
<td>ABO confirmed via two separate sources</td>
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<td>UNOS ID confirmed</td>
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<td>Death pronouncements</td>
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<td>OPO staff initials</td>
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<td>Initials of 2nd person verifying</td>
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</table>

Individuals involved in the verification process must complete the following:

<table>
<thead>
<tr>
<th>PRINTED NAME</th>
<th>SIGNATURE</th>
<th>INITIALS</th>
<th>DATE</th>
<th>TIME</th>
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OPTN
Verification Form

To access the Verification form, go to

http://optn.transplant.hrsa.gov/resources
When Packaging Multiple Organs

- There are specific labels for en bloc kidneys and en bloc lungs
- When multi-visceral or other organ combinations are packaged together the external organ specific labels should be “layered” to show all organs in the package
- All appropriate internal labels should be affixed to the outermost organ bag
Vessels

- A new vessel label has been developed
- Not required by policy until board review and approval in November 2010 (will be available)
- Contains all pertinent information required by OPTN policy
- Label should be attached to the outermost barrier in which the vessels are packaged
  - If vessels stored they must be packaged with triple sterile barriers, one of which must be rigid (per policy 5.4.3)
5.4.3 Vessels

If packaged separately from the organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container; the vessels must be labeled with the standardized internal label distributed by the OPTN contractor. The labeled 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” 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 internal label must be affixed to the outermost barrier.
### Vessel Label

**For Use in Organ Transplantation Only**

<table>
<thead>
<tr>
<th>UNOS ID</th>
<th>-</th>
<th>-</th>
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</thead>
<tbody>
<tr>
<td>DONOR ABO</td>
<td>RECOVERY DATE</td>
<td></td>
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<tr>
<td>ORIGINATING OPO</td>
<td>TEL:</td>
<td></td>
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</tbody>
</table>

#### Infectious Disease Test Results

<table>
<thead>
<tr>
<th>Test</th>
<th>Positive</th>
<th>Negative</th>
<th>Pending</th>
<th>N/A</th>
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</thead>
<tbody>
<tr>
<td>HIV I/II</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>RPR/VDRL</td>
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<td>HBsAg</td>
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<tr>
<td>HBeAb</td>
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<tr>
<td>Anti-HCV</td>
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<td>Anti-CMV</td>
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<td>EBV</td>
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<td>Other</td>
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</tbody>
</table>

These vessels are from a CDC High Risk Donor: [ ] YES  [x] NO

See OPTN Policy 5.0 regarding vessel storage & disposition reporting requirements.

6/2010  VESSELS CAN BE STORED UP TO A MAXIMUM OF 14 DAYS FROM ORIGINAL RECOVERY DATE
Ordering Labels

- Packages of 10 instead of 25 available for purchase starting September 1, 2010
- Labeling system cannot be used until October 1, 2010 and must be used starting January 1, 2011
- Costs to order: (Same as previous labels)
  - External Labels - $8.30 / package
  - Internal Poly Label - $6.10 / package

To Order: https://store.unos.org
Timeline

- September 1, 2010 – All labels will be available in the UNOS Store
- October 1, 2010 – OPOs can begin to use the new label system
- November 9, 2010 – policy changes go to the Board for approval (anticipate BOD approval for requiring the internal label).
- January 1, 2011 – Only new label system can be used.
For Questions

If you have questions or comments, there is a designated mailbox that will be checked daily.

Orgtrans@UNOS.org
Organ Specific Colored Labels

1. Pancreas (Mustard)
2. Right Kidney (Blue)
3. Left Kidney (Yellow)
4. Heart (Red)
5. Intestine (Pink)
6. Left Lung (Purple)
7. Right Lung (Orange)
8. Liver (Green)

OPTN
Organ Specific Colored Labels: Enbloc

Kidneys Enbloc  
(Yellow and Blue)

Lungs Enbloc  
(Orange and Purple)
Assembling Organ Box - Step 1

- 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.
Organ Label

1. UNOS ID
2. Donor ABO
3. Cross Clamp Date and Time
4. Contents of Box
5. Document Ice
6. Originating OPO Info
7. Destination Info (if known at time of packaging)

*Affix Label to Organ Box OPTN
Assembling Organ Box- Step 2

- 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).
Assembling Organ Box - Step 3

- 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).
Organ Packaging Requirements

Three Sterile Barriers

RIGID CONTAINER
Required for Kidneys and Pancreata

OPTN
Organ Packaging - Step 1

- Packaging Options

1. Rigid Container, Bag, Bag
2. Bag, Rigid Container, Bag

*Affix Polyplastic Label to Organ Package
Organ Packaging- Step 2

- Place Properly Labeled Organ in Organ Box with Ice
Organ Packaging - Step 3

- Close Inner Bag
Organ Packaging - Step 4

Place Tissue Typing Material in a Biohazard Bag and Set it on Top of the Closed Inner Bag

**Note:** Do not embed sampling material in ice
Organ Packaging - Step 5

- Close the Styrofoam Lid
Organ Packaging- Step 6

- Complete donor documentation, as described in UNOS Policy 2.5.6.1, must be sent in the container with all transported organs. 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.
Organ Packaging - Step 7

- Ensure the Organ Box is properly Sealed
Vessel Packaging

Required Items

1. Sterile Rigid Container (if packaged separately from organ)
2. 2 Sterile Isolation Bags
3. UNOS Vessel Label
Vessel Packaging (Cont’d)

- *Affix Vessel Label To Vessel Package
Vessel Packaging (Cont’d)

- Place Packaged Vessels in Organ Box with the Organ on Ice
Labeling for Multiple Organs

- When Multiple Organs are Packaged in the same Box....
- Affix Polyplastic labels to respective organ packages
- Stagger Both Organ Labels on the Same Side of the Organ Box Ensuring the Names of Both Organ are Visible
Labeling for Multiple Organs (Cont’d)

- Write the Name of the Associated Organ in the “Other” section on the label of the different organ.
- Complete this step for Both Labels in case One Label Falls Off.
1 ~ Requires transplant centers to notify the recovering OPO when they repackage an organ

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

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.

- This proposed policy will be considered by the Board in November.
- Verbal communication is essential when repackaging an organ.
These labeling policies apply to DECEASED donor organs only

- Policy 5.0 does not mimic Policy 12.0, which is the policy transplant centers use to package living donor organs
- Living donor organs require external labels only
- This has been recognized and is being addressed between the Living Donor Committee and OPO Committee
Questions/Comments

- To ask a question or make a comment, press 1 and 0
- You will be placed in the question queue
- You will be prompted to ask your question when it is your turn
- If you wish to withdraw from the question queue, press 1 and 0