Standardize an Organ Coding System for Tracking of Organs: Requirements for OPO TransNet^{sm} Use

Sponsoring Committee: **Operations and Safety Committee**

Policy/Bylaws Affected: **Policies 1.2 (Definitions), 2.2 (OPO Responsibilities), 16.1 (Organs Recovered by Living Donor Recovery Hospitals), 16.2 (Packaging and Labeling Responsibilities), 16.3.B (Internal Labeling of Organs), 16.3.C (Internal Labeling of Blood and Tissue Typing Materials), 16.3.D (Internal Labeling of Vessels), 16.3.E.ii (Mechanical Preservation Machine), 16.3.F (External Labeling), 16.4.A (Organ Packaging Documentation), and 16.5 (Verification and Recording of Information before Shipping)**

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Problem Statement

In the past, packaging and labeling organs were done entirely by hand, partially by hand, or by using pre-printed labels. Between 2012 and June 2015, labeling errors accounted for 11% of all voluntary OPTN safety reports and packaging or shipping errors made up an additional 11%. These errors can contribute to serious events. There have been at least ten cases involving either actual occurrences or near misses of the wrong organ delivered or wrong organ going to the wrong recipient since 2006.

Summary of Changes

TransNet is a new OPTN system that uses barcode scanning technology at organ recovery to help label, package, and track organs and other materials being shipped for transplantation. Requiring organ packaging and labeling to be completed using TransNet will greatly reduce transcription errors and mistakes due to illegible handwriting. It will allow for one time data entry of donor information and a consistent validation process across all OPOs. TransNet will also accelerate information transfer and improve real-time communication regarding organ package contents and location, thus enabling transplant hospitals to prepare for organ receipt and subsequent organ transplant more efficiently.

Beginning June 1, 2017, OPOs must use TransNet to complete required OPTN labeling and packaging requirements for all deceased donors.

What Members Need to Do

OPOs: OPOs must:

- Purchase the equipment necessary to label deceased donor organs using TransNet if they have not done so already. OPOs that have not completed OPTN training will need to complete instruction and pass the required competency testing. Then they will need to administer both training and field competency training to their own OPO staff who label and package organs.

- Modify their internal protocols to incorporate TransNet into their labeling and packaging procedures. They will also need to identify and test a back-up system in the event they cannot use TransNet temporarily. This written protocol must fulfill all the requirements *in Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*, and the host OPO must document the reasons why they did not use the OPTN organ tracking system.
- Print a donor ID band and scan the donor ID band at the beginning of each deceased donor case. They will need to use TransNet to complete all required OPTN internal and external labels (except for the sterile internal vessels label), including the waterproof container, that holds the accompanying organ documentation.
- Modify their practice to include scanning all items packaged and transported for transplant including the organ, extra vessels, blood specimens, biopsy specimens, tissue specimens (e.g. spleen, nodes, etc.), and paperwork. They will need to scan the final shipping label and submit the case information to UNOS. Internet connectivity is required to download the donor information from DonorNet® and upload the information to UNOS. All other TransNet functions can be completed without internet connectivity.

Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

1.2 Definitions

OPTN organ tracking system
A software application developed and distributed by the OPTN Contractor that uses barcode technology to generate printed labels for organ packaging and tracking.

2.2 OPO Responsibilities

The host OPO is also responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Clinical management of the deceased donor.
8. Assuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
11. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.
12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
13. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN Contractor upon receipt to enable complete and accurate evaluation of donor suitability by

transplant programs:

a. ABO source documentation
b. ABO subtype source documentation
c. Infectious disease results source documentation
d. Death pronouncement source documentation
e. Authorization for donation source documentation
f. Human leukocyte antigen (HLA) type
g. Donor evaluation and management
h. Donor medical and behavioral history
i. Organ intraoperative findings

14. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

16.1 ~~Organs Recovered by~~ Packaging and Labeling Requirements for Living Donor ~~Recovery Hospitals~~ Organs and Vessels

Living donor recovery hospitals ~~must follow all of the requirements~~ are responsible for packaging, labeling, and transporting living donor organs, ~~tissue typing material, and~~ vessels, and tissue typing samples according to ~~this~~ *Policy 16*, with these differences:

~~1. While OPOs are responsible for packaging, labeling, and transporting deceased donor organs, vessels, and tissue typing samples, recovery hospitals are responsible for packaging, labeling, and transporting living donor organs, vessels, and tissue typing samples.~~

1.~~2.~~ Members are not required to use the OPTN organ tracking system for labeling and packaging living donor organs, vessels, and tissue typing samples.

2~~3~~. When a member repackages a living donor organ, they are not required to notify the member that originally packaged the organ.

3. In addition to the list of documents in *Policy 16.4: Documentation Accompanying the Organ or Vessel*, living donor organs must contain the blood type source documents, donor informed consent form, and the complete medical record of the living donor. Vessels that are shipped separately from living donor organs must include the same documents as are required for shipping living donor organs.

4. Blood samples and tissue typing materials must contain the donor ID and *one* of the following ~~three~~ identifiers: donor date of birth, donor initials, or a locally assigned unique ID. Each sample must contain the donor's blood type and subtype, the type of tissue, and the date and time when the sample was obtained. The recovery hospital must document in the donor record all unique identifiers used to label blood samples and tissue typing materials.

5. The recovery hospital will provide specimens for tissue typing if requested. The minimum typing materials for living donor kidneys are two ACD (yellow top) tubes per kidney.

16.2 Packaging and Labeling Responsibilities

The host OPO or recovery hospital is responsible for packaging and labeling organs, tissue typing material, and vessels that travel outside the recovery facilities. The host OPO or recovery hospital must make reasonable efforts to package and label organs, tissue typing specimens, and vessels in a timely fashion.

~~If a transplant hospital repackages an organ for transport, it must package, label, and transport the organ according to this Policy and immediately notify the host OPO of the repackaging.~~

The host OPO must complete labeling and packaging using the OPTN organ tracking system. The OPO must develop and comply with a written protocol for an alternative labeling and packaging process if, for any temporary reason, the OPTN organ tracking system is not used. This written protocol must fulfill all the requirements in *Policy 16* and the host OPO must document the reasons the OPTN organ tracking system was not used.

Transplant hospital staff may not leave the operating room without allowing the host OPO to package and label deceased donor organs, tissue typing specimens, and vessels as required ~~according to this Policy. If a transplant hospital fails to comply with this Policy~~, or the host OPO ~~must~~ will be required to submit a report about the event through the OPTN Improving Patient Safety Portal.

If a transplant hospital repackages an organ for transport, it must package, label, and transport the organ according to the requirements in *Policy 16*, except that the use of the OPTN organ tracking system is not required. The transplant hospital must immediately notify the host OPO of the repackaging.

16.3 Packaging and Labeling

The host OPO must package all organs, tissue typing material, and vessels in a sterile environment using universal precautions.

The packaged organs from the deceased or living 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. The host OPO may either package vessels with or separate from organs.

The transplant hospital ~~center~~ or OPO must use both internal and external transport containers to package a deceased or living donor organ that travels outside of the facility where the organ is recovered.

16.3.B Internal Labeling of Organs

The ~~H~~host OPO must securely attach the completed OPTN internal label, identifying the specific contents, to the outer-most layer of the triple sterile barrier or cassette of mechanical preservation machine holding each organ. The OPTN Contractor distributes a standardized label that must be used for this purpose. The internal label must be completed using the OPTN organ tracking system. The label must include ~~In addition to the~~ a description of the ~~specific~~ contents of the package, ~~the label information must include~~ the donor ID, and donor blood type and blood subtype, if used for allocation.

16.3.C Internal Labeling of Blood and Tissue Typing Materials

Each separate specimen container of blood or tissue typing material must have a label that will remain secured to the container under normal conditions of transport. If the blood and tissue typing materials will be accompanying the organ, the internal label must be completed using the OPTN organ tracking system. The label must include the donor ID and at least *one* of the following identifiers:

- Locally assigned unique ID
- Donor date of birth
- Donor initials

Additionally each specimen should be labeled with *both* of the following:

1. The date and time the sample was procured

2. The type of tissue

The donor blood type and subtype, if used for allocation, should be included on tissue typing material and blood samples if known. If the donor ID or blood type is not available during the preliminary evaluation of a donor, a locally assigned unique ID and one other identifier for the transportation of initial screening specimens may be used. The OPO must document in the OPO donor record all unique identifiers used to label tissue typing specimens.

16.3.D Internal Labeling of Vessels

The rigid container holding the vessels and the outermost layer of the triple sterile barrier must each have a completed OPTN vessel label. The OPTN Contractor distributes standardized labels that must be used for this purpose. The internal label on the outermost layer of the triple sterile barrier must be completed using the OPTN organ tracking system. The labels must ~~contain~~ include *all* of the following information according to *Table 16-1* below.

Table 16-1: Required Information on Internal Labels for Vessels

This information must be included:	On the rigid container:	On the outermost layer of the triple sterile barrier:
1. Donor ID	●	●
2. Donor blood type	●	●
3. Donor blood subtype, if used for allocation	●	●
4. Recovery date	●	●
5. Description of the container contents	●	●
6. That the vessel is for use in organ transplantation only	●	●
7. All infectious disease testing results		●
8. Whether the vessels are from a donor with a positive result (including NAT) for *any* of the following: • **Human Immunodeficiency Virus (HIV), Hepatitis C virus (HCV), or Hepatitis B Virus (HBsAg or NAT)** • **Hepatitis B virus (HBcAb)**	●	
9. Whether the vessels are from a donor that meets the increased risk for disease transmission criteria in the *U.S. Public Health Service (PHS) Guideline*	●	●

16.3.E.ii Mechanical Preservation Machine

~~When transporting an organ using~~ Members may use a mechanical preservation machine~~, the cassette~~

~~containing the organ must be labeled with the organ type, UNOS ID, blood type, and blood subtype if used for allocation. Mechanical preservation machines may be reused only if all labels from previous donor organs are removed~~ to transport organs. A mechanical preservation machine may be reused only if it is properly cleaned and sanitized and all labels from previous donor organs are removed.

16.3.F External Labeling

A label, that under normal conditions of transport will remain secured, must be attached to the outside of the external transport container. Disposable shipping boxes, coolers, and mechanical preservation machines must have the OPTN external label. The OPTN Contractor distributes a standardized label that must be used for this purpose.

The OPTN external label must be completed using the OPTN organ tracking system. The label must ~~contain~~ include *all* of the following:

1. The donor ID
2. The sender's name and telephone number
3. The donor's blood type
4. The donor's subtype, if used for allocation
5. A description of the specific contents of the box
6. The Organ Center's telephone number

16.4.A Organ Packaging Documentation Requirements

Each external deceased and living donor transport container holding an organ must be sent with *all* of the following source documentation:

1. Blood type
2. Blood subtype, if used for allocation
3. Infectious disease testing results available at the time of organ packaging

The source documentation must be placed in a watertight container in *either* of the following:

- A location specifically designed for documentation
- Between the inner and external transport containers

For deceased donor organs, the host OPO must label the watertight container. This label must be completed using the OPTN organ tracking system. The label must include the donor ID, blood type, and blood subtype if used for allocation.

16.5 Verification and Recording of Information before Shipping

Each OPO or recovery hospital must establish and then implement a protocol for verifying the accuracy of organ and vessel packaging labels by an individual other than the individual initially performing the labeling and documentation.

This verification must occur after completing the required labels and documentation for organs and vessels and the host OPO or recovery hospital must document that verification.

The host OPO must use the OPTN organ tracking system to:

1. Record each item placed into the external organ package

2. Report to the OPTN Contractor that the package is ready for tracking