

*OPTN/UNOS Operations and Safety Committee*

# Standardize an Organ Coding System for Tracking of Organs: Requirements for OPO TransNet Use

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# Standardize an Organ Coding System for Tracking of Organs: Requirements for OPO TransNet Use

## Executive Summary

The Operations and Safety Committee is proposing a requirement for organ procurement organizations (OPOs) to use TransNet<sup>sm</sup> for deceased donor organ labeling and packaging. The proposal also requires OPOs to transmit case data to the OPTN to allow for web-based tracking while organs are in transit.

TransNet, a service of the OPTN, is a new system that uses barcode scanning technology at the point of organ recovery to help label, package, and track organs and other biologic materials being shipped for transplantation.

TransNet involves using an application developed for either Android or iOS tablets and a portable barcode printer that interacts with DonorNet<sup>®</sup> to supplement the current UNOS labeling system. During organ recovery, OPO procurement coordinators will use the system in the operating room to print on-demand labels and scan information on all organs and materials to be transported. Currently, 46 out of 58 OPOs have been trained to use TransNet on a voluntary basis. This proposal will make use of the system a requirement for all OPOs.

Requiring OPOs to use TransNet will reduce packaging and labeling errors. Packaging and labeling organs were done in the past entirely by hand, partially by hand, or by using pre-printed labels. Automating the process with 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 impending organ transplants more efficiently.

This proposal primarily supports OPTN/UNOS Strategic Goal 4: Promote living donor and transplant recipient safety by reducing labeling, packaging, and communication errors that can result in wrong recipient transplant, or organ wastage.

# Standardize an Organ Coding System for Tracking of Organs: Requirements for OPO TransNet Use

*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 Documentation, and 16.5 Verification of Information before Shipping

*Sponsoring Committee:* Operations and Safety Committee

*Public Comment Period:* January 25, 2016 – March 25, 2016

## What problem will this proposal solve?

Important information is collected and presented to a hospital when a donor is identified and organs are allocated. How this information is shared, and how recipient and donor variables are analyzed vary from hospital to hospital according to local practice. This creates issues related to organ transportation, transcription, and data entry errors, and miscommunications that can lead to decreased organ utilization.

Organ labeling and packaging errors are a recurrent problem observed in transplantation. Root causes may stem from reliance on human actions without built in safeguards.<sup>1</sup> The OPTN collects voluntary patient safety situation reports. Between 2012 and June 2015, labeling errors accounted for 11% and packaging/ shipping errors made up an additional 11% of all voluntary safety reports. These equaled 136 unique labeling and 82 unique packaging/shipping safety situations reported. At least 22 organs associated with these errors were either not recovered or not transplanted.

There have been at least ten cases involving either occurrences or near misses of wrong organ delivered or wrong organ/wrong candidate since 2006. There have been cases where the wrong organ was labeled and packaged incorrectly. There have been cases in which the right organ was delivered but transplanted into the wrong patient. In addition, there have been 22 switched kidney laterality cases since 2012 with four resulting in organ discards. These cases represent unnecessary and preventable organ waste.

True error rates surrounding near miss and adverse events are not fully known. Nationally, it is estimated that only 5% to 15% of health care patient safety events are reported through incident reporting

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<sup>1</sup> M.G. Ison, J.L. Holl, and D. Ladner, "Preventable errors in organ transplantation: an emerging patient safety issue?" *American Journal of Transplantation* 9 (2012):2307-12, accessed December 18, 2015, doi: 10.1111/j.1600-6143.2012.04139.x.

systems.<sup>2,3</sup> A 2014 UNOS analysis estimated that only 13% of actual safety events are reported to the OPTN.

Failure Modes and Effects Analysis (FMEA) is a risk assessment technique to identify and rank potential target steps in the process needing improvement. A Failure Modes Effects and Criticality Analysis (FMECA - an extension of the FMEA process) was conducted by Northwestern University in 2013 to examine the transplantation process from referral through post-recovery phases. Over 40 transplant and hospital professionals worked on the FMECA. They mapped out the entire process and potential failure modes. In addition, they systematically identified the potential causes of the failure, frequency of the failure, severity or consequence (effect) of the failure on a donor and/or recipient, and detection of the failure by the existing safeguards or controls. By combining the occurrence and severity scores, each failure was assigned a level of criticality. Furthermore, scores were combined to create the Risk Priority Number (RPN) to suggest key areas for process improvement and system redesign. The FMECA identified 146 unique vulnerabilities or failures resulting from 60 identified process steps and revealed multiple failures in the labeling and identification steps of the deceased donor organ procurement process. Highly critical steps identified in the process include accuracy of donor information on labels, identification of the laterality of a kidney, and validation of receipt of the “right” donor organ for the “right” recipient.

Handwriting of labels is prone to transcription errors and takes time away from other needed tasks. A label that contains both print and bar code labels, as produced with TransNet, addresses these types of errors.

Unrelated to these labeling types of errors, transportation issues also impact transplantation. The UNOS Organ Center (OC) tracks transportation failures and near misses for placements that they have facilitated. Between July 2014 and June 2015, the OC facilitated 2,445 shipments. There were 28 shipment failures. Failures are defined as when the shipped organ(s) did not make it to the original intended destination or the organ(s) arrived at the original intended destination but with a delay significant enough to be unacceptable for transplant. Out of the 36 organs involved in the 28 shipment failures, 30 (83%) organs were discarded. Some issues involved in these failures included courier not available to initiate a shipment; OPO shipped wrong kidney; airline computer system issues causing cargo to be disallowed; and courier delay due to traffic resulting in a missed flight.

The OC also tracks near misses, which are defined as delays of two or more hours from the original estimated time of arrival. Between July 2014 and June 2015, there were 109 near misses with delays ranging from 2 to 12 hours. The primary reasons noted were weather, mechanical failure, or transport cancellation. Over 25% were due to a driver/courier issue and 11% were due to a transplant hospital/OPO issue. Some of these situations leading to a near miss were incorrect pickup address provided; blood shipment lost in transit; courier missed flight; and package not ready for transport at the agreed upon time.

Transplant hospitals do not currently have access to real time information regarding organ shipments. Communication occurs via phone or email but there is no systematic approach to tracking organs in transit. This can hamper the ability of transplant hospitals to plan efficiently and effectively for the upcoming transplant surgery upon organ arrival. Errors have been reported to the patient safety system where organ location has been lost resulting in increased cold ischemia time (CIT).

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<sup>2</sup> Osnat Levtzion-Korach, et al., “Integrating incident data from five reporting systems to assess patient safety: Making sense of the elephant.” *Joint Commission Journal on Quality and Patient Safety / Joint Commission Resources* 9 (2010):402-10.

<sup>3</sup> Charles Vincent, Susan Burnett, and Jane Carthey, “Safety measurement and monitoring in healthcare: a framework to guide clinical teams and healthcare organizations in maintaining safety,” *British Medical Journal of Quality and Safety*. 23 (2014):670-7, accessed December 18, 2015 at <http://qualitysafety.bmj.com/content/23/8/670.full.pdf+html>.

Transportation of organs will likely continue to increase. Since the new Kidney Allocation System was implemented in December 2014, more kidneys are now being shared across donor service area (DSA) boundaries. Previously about 20 percent of kidneys were transplanted outside of the recovering OPO's DSA, and this has increased to about 32 percent under KAS.<sup>4</sup>

The TransNet system provides real time information on package contents as well as location tracking using latitude and longitude points. Use of actual Global Positioning System (GPS) devices within organ packages is also under consideration as a future enhancement.

Together these data provide evidence for areas needing improvement for labeling, packaging, shipping and ultimately transplanting the right organ into the right recipient.

## Why should you support this proposal?

The current process of labeling and packaging organs is done either entirely with handwritten labels, with partially handwritten labels, or by using pre-printed labels. Automating the process with print-on-demand labels will greatly reduce the chance of transcription errors and mistakes due to illegible handwriting and allow for one time data entry of donor information and a consistent validation process across all OPOs. A comprehensive electronic solution will help ensure that donated organs are labeled and matched both correctly and efficiently with the identified recipient.

TransNet is a new system that uses barcode scanning technology at the point of organ recovery to help label, package, and track organs and other biologic materials being shipped for transplantation. It uses an application developed for either an Android or iOS tablet and a portable barcode printer that interacts with DonorNet to supplement the current OPTN/UNOS labeling system. During the organ recovery process, OPO procurement coordinators will use the system in the operating room to print on-demand labels and scan the information on all organs and materials to be transported. Clinical coordinators also can use it in the ICU, before organs are even recovered, to label blood tubes and other samples.

TransNet provides functionality and improvements in the following areas:

1. Donor Management
  - a. Workflow (Order and process for work steps)
  - b. Enhanced Validation
  - c. Vessel Label Entry
  - d. Print on Demand
2. Operating Room (OR)
  - a. Workflow (Order and process for work steps)
  - b. Print on Demand
3. Post OR
  - a. Package (Shipping Labels and Barcode; Box Contents)
  - b. Ship – Scan When Ready to Ship
4. Transport
  - a. Email, Text Alerts
  - b. Scan – Ready to Ship
  - c. Scan – Receipt

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<sup>4</sup> Organ Procurement and Transplantation Network. Accessed June 2, 2016, <https://optn.transplant.hrsa.gov/news/analysis-shows-kidney-allocation-system-achieving-key-goals/>

5. Transplant Center
  - a. Print Recipient ID Band
  - b. Receive Organ
  - c. Match Organ to Recipient

Over half of all OPOs have received TransNet training. As of May 12, 2016, 46 out of 58 (79%) OPOs have completed the three-day required training including passing a proficiency test. An additional eight OPOs have signed up for future training dates.

The training has been successful. Attendee evaluations gave the training high marks to prepare them to implement the system. Out of nine trainings conducted between March 2015 and April 2016, the average of individual training scores for “The material was presented in an organized manner” and “The program addressed timely information needed to perform my job” was 4.9 out of a scale of 1 (lowest) to 5 (highest). Pre and post ratings also demonstrated increased ability to use the system. See **Table 1** below.

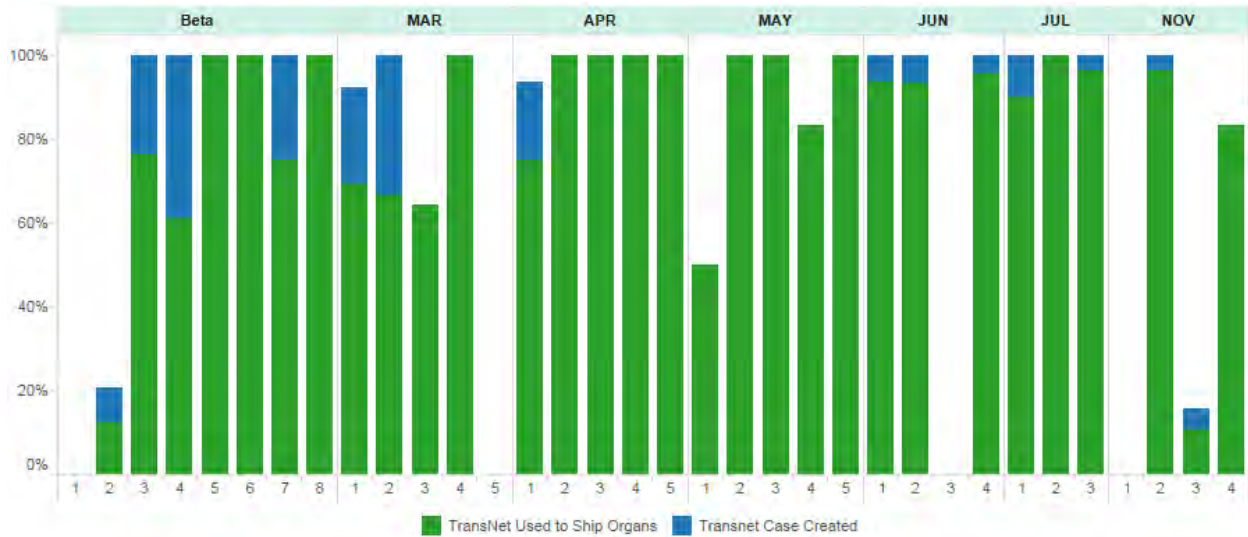
**Table 1: TransNet Training Evaluation Scores**

| Skill  | Before the event,<br>please rate your<br>ability to: | After the event,<br>please rate your<br>ability to: | Increase |
|--|--|---|----------|
| 1. Describe the basic tablet and printer set up for TransNet                           | 2.5  | 4.8   | +2.3     |
| 2. Explain the essential flow of the TransNet process                                  | 2.4  | 4.7   | +2.3     |
| 3. Describe the development and purpose of the overall TransNet application and tools. | 2.6  | 4.6   | +2.0     |
| 4. Demonstrate the proficiencies needed to execute the TransNet process                | 2.3  | 4.7   | +2.4     |

Use of TransNet continues to grow. A voluntary nationwide deployment started in March 2015 following pilot and beta testing. From September 18, 2014 – January 31, 2016, TransNet was used to package 8,392 organs from 2,595 deceased donors. A study of individual OPO usage showed that a TransNet case was created for 76.6% of all deceased donors recovered during January 2016 by the 33 trained OPOs. Twenty-two OPOs (67%) from this cohort created TransNet cases for every donor recovered. Two OPOs had not used TransNet for any cases and these sites have received individual follow up and technical assistance.

**Figure 1** shows individual OPO TransNet usage for deceased donors recovered in January 2016. Of the 34 OPOs trained between September 2014 and November 2015, the majority used TransNet to create at least 80% of their cases.

**Figure 1. TransNet Usage for Deceased Donors Recovered in January 2016 by OPO- Percent of Actual Donor Cases (OPOs Trained September 2014 – November 2015), Training Groups Beta - Nov**



The Committee developed a survey conducted by the Association of Organ Procurement Organizations (AOPO) in September 2015 to assess OPO intentions to attend training and use TransNet. Ten OPOs indicated their plans were contingent upon other factors. The two primary reasons for non-commitment were waiting for product availability in iOS (n = 5) and waiting to hear more feedback from the OPO community (n=3). The iOS version of TransNet was released in January 2016 to meet OPO community needs. Only two OPOs indicated that they did not plan to sign up or use TransNet. One of these OPOs hosted a west coast training April 2016. Five OPOs did not respond to the survey, however, one of these OPOs is a current user. Overall, these survey results support the widespread acceptance and willingness to adopt TransNet.

TransNet is an effective electronic system to address the problems identified. Extensive research and observation was used in the development of the system. Community input and responsiveness to programming enhancements makes TransNet an ideal solution. Peer-reviewed literature supports development of this type of product as cited in the supporting evidence section.

In addition to being a tool for quality improvement, TransNet will provide a more efficient method to fulfill several policy requirements. The labeling flow and function of TransNet will assure that OPOs complete all labeling fields required by policy. The printed donor ID band and subsequent barcode scan using TransNet will fulfill part of ABO verification requirements going into effect June 23, 2016. In March 2016, functionality was released that enables the system to be used for validation of labels required by both OPTN/UNOS and Centers for Medicaid and Medicare Services (CMS) policies. Reporting will also be provided that will enable OPOs to conduct their own data monitoring for metrics and other needed information.

More information about TransNet is available for the community.<sup>5</sup>

In summary, the benefits of mandatory OPO TransNet use will be:

<sup>5</sup> <https://www.transplantpro.org/technology/transnet/>

1. Reduction of labeling and packing/shipping errors
2. Elimination of some labeling errors (e.g. transcription)
3. Standardization on labeling and packaging information for all organs
4. Increased reliability of information provided to transplant hospitals
5. Streamlined workflow and minimized complexity of recovery processes
6. Increased ability to troubleshoot packaging, labeling, and transport issues
7. Availability of real-time information about organs in transit
8. Ability to expand TransNet benefits to transplant hospitals. (Without complete use by all OPOs, transplant hospitals may need to two different processes to conduct required organ check in and verifications.)
9. Increased ability to match right organ to right recipient

## How was this proposal developed?

This project started in fall 2012 as a HRSA project with funding from an HHS Innovations program. It was one of four HHS programs intended to drive innovation in the government and healthcare. A HRSA Innovations Fellow with significant experience in packaging and shipping was hired to help lead the efforts. The project received special dedicated funds through a specific contract modification to the OPTN through September 2015.

The project goals were to:

- Reduce incorrect transplantation by
  - Eliminating transcription errors
  - Eliminating legibility errors
  - Minimizing complexity
- Minimize transport errors
- Accelerate organ information transfer
- Capture organ procurement/transport data

An Ad Hoc Organ Tracking Committee was formed with representatives from the Operations and Safety, OPO, Transplant Administrators, and Transplant Coordinators Committees. In addition, subject matter experts in human factors engineering, blood banking, tissue banking, and eye banking were included. They observed numerous organ recoveries and transplantations with a focus on the labeling, packaging, transport, and receipt processes.

The team leveraged the Lean Startup methodology by understanding and learning the business problem and requirements through direct observations and instant immersion. The core idea of lean methodology is to maximize customer value while minimizing waste. This led to a proof of concept prototype application that provided electronic labeling, scanning, tracking, and receipt functions on an Android tablet. Three simulated recoveries and transplants were also conducted to develop further this proof of concept and test the prototype. Rapid agile application development was used to improve the application continuously. Using an agile development method, multiple versions were rapidly produced in response to feedback leading to an improved product launched for pilot testing among five OPOs in summer 2013.

Following the pilots and subsequent improvements, beta testing was commenced for eight OPOs in 2014. In March 2015, the OPO TransNet version was released for a voluntary nationwide deployment. Getting TransNet to this point incorporated extensive coordination and collaboration with OPOs and transplant hospitals as well as professional organizations such as AOPO and NATCO. The TransNet team has presented at multiple professional society venues. The AOPO IT council has indicated support for TransNet. They have offered to assist OPOs purchase bulk supplies if needed. The Operations and Safety Committee continues to operate a subcommittee that meets monthly and includes the Chair of the OPO Committee, system users, and committee representatives to guide project development. The OPO Committee has reviewed this proposal and indicated support.



## How well does this proposal address the problem statement?

The FMECA found that the early prototype of TransNet would affect 42 or 29% of the potential failures identified during the deceased donor recovery process. Some process failures were deemed to be eliminated (e.g. “label unreadable or illegible”) with use of the application. The application addresses areas of key importance or high risk for failure/impact. A donor ID band will help address five failure points with a severity score of eight or higher on a scale of one to ten. The TransNet early version decreased risks identified with six of ten key identified processes. See **Table 2**.

**Table 2: Key Processes Affected by New Technology**

| Process Description                                      | Affected by New Technology? |
|--|-----------------------------|
| Complete packaging                                       | Yes – risk decreased        |
| Record clamp time  | Yes – risk decreased        |
| Package/label lymph nodes traveling with organ           | Yes – risk decreased        |
| Print non-standard labels (for internal standard labels) | Yes – risk decreased        |
| Apply internal standard label                            | Yes – risk decreased        |
| Handwrite on external label                              | Yes – risk decreased        |
| Generate OPTN number                                     | No impact                   |
| Enter preliminary crossmatch results in DonorNet         | No impact                   |
| Enter HLA results into DonorNet                          | No impact                   |
| Enter second ABO result into DonorNet                    | No impact                   |

The FMECA found great potential for use of the tablet application and wireless printer to produce barcoded labels. It noted that use of this technology would result in significant workflow changes to the deceased donor organ procurement, labeling and identification, and transfer process. Five new process controls will be gained by implementing the technology. However, new potential failures may also be introduced. The lab-based simulations provided evidence of both new process controls and new potential failures. **Table 3** describes the gains and possible new risks.

**Table 3: New functionality and process gained with application**

| Functionality   | Description  |
|---|--|
| <b>1. Tablet “on-demand” printing capability</b>  |  |
| <i>New preventive process controls gained</i>   | <i>New potential failure introduced</i>  |
| Eliminates illegible labels   | Risk of labels being printed on the wrong size label and missing information if information does not entirely fit on small label |
| Eliminates the need for visual inspection and comparison of information of every blood tube label |  |
| Reduces the risk of using old labels or mixing up pre-printed labels                              |  |
| Reduces the risk of an incorrect label being applied  |  |
| <b>2. Tablet scanning capability</b>  |  |
| <i>New detective and preventive process controls gained</i>                                       | <i>New potential failure introduced</i>  |
| Reduces the risk of missing items when packaging  | Risk of scanning an item, but not putting it into the box, due to a distraction.   |

| <b>Functionality</b>  | <b>Description</b>  |
|---|---|
| Reduces the risk of incorrect items being packed if “single-piece” work flow is followed when packing organs                    |   |
| Reduces the risk of items with incorrect label packed if “single-piece” work flow is followed when labeling and packing organs  |   |
| <b>3. Double entry electronic verification capability</b>   |   |
| <i>New detective and preventive process controls gained</i>   | <i>New potential failure introduced</i>   |
| Reduces the risk of typing or data entry error for ABO, Donor ID#, Serology results on labels                                   | Incorrect verification: first person completes second person independent verification |
| Eliminates the need to verify ABO and Donor ID# every time a label is created or printed  |   |
| <b>4. Donor identification with ID band with scanning capability</b>  |   |
| <i>New detective and preventive process controls gained</i>   | <i>New potential failure introduced</i>   |
| Reduces the risk of obtaining blood samples from the incorrect patient  | Applying incorrect donor band to donors with similar names                            |
| Reduces the risk of moving the wrong donor to the wrong OR  |   |
| <b>5. “Single-[organ] piece” workflow</b>   |   |
| <i>New detective and preventive process controls gained</i>   | <i>New potential failure introduced</i>   |
| In combination with on-demand printing, it reduces the risk of applying the wrong label on organ packaging                      |   |
| In combination with on-demand printing and scanning capability, it reduces the risk of packing and transporting the wrong organ |   |
| Increases the probability of noticing errors in real-time   |   |

Following feedback from the FMECA, the pilot version was developed and launched. Pilot users found that the system was both safer and more efficient than their current systems according to survey feedback collected after each case. The majority of the coordinators (77%) responded that they agreed that the system in the OR was safer than their current system. Most (68%) of the coordinators agreed that the system was more efficient than their current system in the OR. These pilot survey results supported that the application was addressing problems identified. Feedback was used to make further improvements for the version developed for voluntary nationwide deployment.

A system that can provide point of care labeling is seen as best practice. “On-demand printing of barcoded labels and wristbands at the point of care ensures that labels don’t get lost, left behind in rooms after patients are discharged, or attached to wrong items. It also reduces risk of safety-compromising clinician error resulting from distractions, interruptions, and heavy workload. Busy clinicians need to be able to quickly, easily, and accurately scan and print barcodes the first time.”<sup>6</sup> TransNet provides point of care on-demand labeling as identified as best practice.

The TransNet solution has many benefits and addresses multiple issues identified. OPOs will have a system that generates a donor ID band with barcoded and human readable information to help assure the

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<sup>6</sup> David Crist, “Point-of-Care Labeling: Better Barcoding,” *Patient Safety and Quality Healthcare* 4 (2015): 47-48, accessed on December 18, 2015, <http://psqh.com/march-april-2015/point-of-care-labeling-better-barcoding>.

correct donor is recovered. Labels will be generated in real-time with both a bar code and human readable text. Organ labels and material accompanying the organ will be scanned prior to packaging. The original scan from the donor ID band will assure that labels used are from the correct donor. Scanning will also create a manifest of all items shipped.

Transplant hospitals can scan bar-coded labels against a TransNet generated recipient ID band to assure correct placement and compatibility should they choose to use the system. The system can also serve as documentation. Scanning takes away most risk for human error. The process can also reduce time to complete verifications, prevent transcription errors or misinformation due to direct import of data from UNet<sup>sm</sup>, and create other efficiencies.

The risks of error during manual transcription of information are well documented. In the blood transfusion field, incorrect blood components transfused are a major adverse event. Use of electronic information capture can improve safety by eliminating the risk of manual transcription error and speeding up the information transfer process.<sup>7</sup>

Counting and preventing errors has been challenging in various health care areas. The FDA estimates that 414 blood transfusion errors occur annually. In one study, nearly 80% of these were related to bedside or labeling errors. Point-of-care bedside bar-coding applications are being integrated with blood product administration activities to combine patient identification, medication, and product verification.<sup>8</sup>

Barcoding has been demonstrated to help with another aspect in transplant care. Solid organ transplant recipients are prescribed a high number of medications, increasing the potential for medication errors. Barcode-assisted medication administration (BCMA) has been shown to reduce medication administration errors. BCMA use reduced the medication administration error rate in one organ transplant unit from a baseline of 4.8% down to 1.5%, a 68% reduction.<sup>9</sup>

When integrated with electronic medication administration records, barcode systems are associated with complete elimination of transcription errors. Furthermore, barcode-assisted dispensing systems are associated with 93% to 96% reductions in dispensing errors, and 85% reductions in potential adverse drug events in dispensing. Most studies have reported large and significant reductions in administration errors by up to 80% after implementation of barcode medication administration systems.<sup>10</sup>

Regulations have been developed based on the benefits of bar-coding utilization. In February 2004, the U.S. Food and Drug Administration (FDA) published a final rule (69 FR 9120) requiring certain human drug and biological products to have on their labels a linear bar code that contains, at a minimum, the drug's NDC number (21 CFR 201.25). The rule also requires the use of machine-readable information on blood and blood component labels (21 CFR 606.121(c) (13)). The FDA anticipated that intended mandatory use would reduce errors in hospitals and health care settings.

FDA is establishing a unique device identification system to identify medical devices. The UDI Rule, establishing the unique device identification system, was published on September 24, 2013 (78 FR 139 58786) (the UDI Rule) and will be phased in over seven years. It requires that the label and each device package of a medical device distributed in the United States bear a unique device identifier (UDI), unless an exception or alternative applies. When fully implemented, most device labels will include a UDI in

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<sup>7</sup> D Michael Strong and Naoshi Shinozaki, "Coding and traceability for cells, tissues and organs for transplantation," *Cell Tissue Bank*. 11 (2010): 305–323, accessed on December 18, 2015, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3012207/>.

<sup>8</sup> Cindy Dubin, "Technology, Vigilance, and Blood Transfusions: How U.S. Hospitals and the Federal Government Are Working to Reduce Adverse Events," *Pharmacy and Therapeutics Journal* 7 (2010):374-376, accessed December 18, 2015, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2912004/>.

<sup>9</sup> Joseph Bonkowski, et. al, "Improving medication administration safety in solid organ transplant patients through barcode-assisted medication administration," *American Journal of Medical Quality* 29 (2014): 236-41.

<sup>10</sup> Alexander A Leung, et. al, "A safe practice standard for barcode technology," *Journal of Patient Safety* 11(2015):89-99.

human and machine-readable (bar code) form. The FDA indicates that UDI implementation will improve patient safety, modernize device surveillance, and facilitate medical device innovation.

Coding also will assist with future traceability efforts. It is important to recognize that a coding system does not itself provide traceability, but provides the information infrastructure on which effective traceability can be built. Coding and traceability support each other<sup>11</sup>.

Employing automated point of care human readable and bar code printed labels in organ transplantation through TransNet use utilizes best practice and peer reviewed solution. It provides the foundation for continued quality improvement on the transplant hospital side. Not using TransNet would save some equipment purchasing costs and training efforts on behalf of OPOs and programming efforts on behalf of the OPTN. The benefits of using TransNet are supported through public comment, current voluntary use, and use of best practice.

## Was this proposal changed in response to public comment?

Several major themes arose in public comment with several post-public comment changes that clarified use. Some additional non-substantive style, consistency, and clarity edits were also made.

### 1. Overall support for the proposal

The proposal was well received in public comment. All regions unanimously supported the proposal except Region 5. Region 5 passed the proposal but had two “no” votes.

American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), American Society for Histocompatibility and Immunogenetics (ASHI), and NATCO all support the proposal. AOPO sent in a letter of support after the end of public comment.

The OPO Committee supports the proposal.

Two individual OPOs also made comments of support.

### 2. Request to extend TransNet usage to transplant hospitals

Eight comments were made urging the development and use of TransNet by transplant hospitals in order to gain the full benefits of the system. ASTS requested “a timeline for the development and implementation of the “complete” electronic tracking system that will facilitate tracking from donor to recipient (and not just a simple inventory system)”.

The OSC wholeheartedly agrees and is committed to working on this next step.

Region 6, AST and ASTS requested that this development include performing required verifications (e.g. ABO) using TransNet.

The OSC wholeheartedly agrees and is committed to working on this next step.

### 3. Request to clarify TransNet usage in specific situations

The Living Donor Committee requested that functionality be developed for use with living donor organs. Requirements gathering has started for living donor organs.

It was requested that clarification be made on whether OPOs who package living donor organs on behalf of living donor recovery hospitals would be required to use TransNet in this situation. Because functionality does not currently exist for use with living donor organs, a post-public comment clarification was made to the policy proposal that exempts mandatory use for living

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<sup>11</sup> D Michael Strong and Naoshi Shinozaki, “Coding and traceability for cells, tissues and organs for transplantation,” *Cell Tissue Bank*. 11 (2010): 305–323, accessed on December 18, 2015, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3012207/>.

donor organs. As this functionality is developed, OPOs and living donor recovery hospitals will be able to test TransNet without violating the proposed policy language.

It was also requested that language be clarified regarding the repackaging of organs and TransNet use. The Committee also developed post-public comment exclusionary language for the repackaging of organs as this function may be performed by transplant hospitals. Currently the functionality for transplant hospitals to repackage organs using TransNet does not exist.

The Committee also considered special situations such as third-party organizations that may perform organ perfusion such as ex-vivo lung perfusion. Current OPTN policy does not specifically address these types of organizations in general and therefore specific policy regarding TransNet usage for these groups is not proposed. If a third-party organization were to perfuse on behalf of an OPO, it would be required to use TransNet by delegation of responsibility. If a third party organization were to perfuse on behalf of a transplant hospital, then use of TransNet would not be required at this time due to the repackaging exemption.

## Which populations are impacted by this proposal?

This proposal will impact deceased donor organs that are recovered and transported outside of the recipient transplant facility. In 2015, there were 9,080 deceased donors (60% of all donors). That same year there were 24,980 transplants using deceased donor organs. These figures are based on OPTN data as of April 29, 2016. This proposal would improve labeling, packaging, shipping, and overall workflow for the recovery and transportation of all deceased donor organs.

## How does this proposal support the OPTN Strategic Plan?

This proposal supports the OPTN Strategic Plan as follows:

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* There is no impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* This is the primary strategic goal for this proposal; the project supports this goal by:
  - Reducing errors related to transcription and readability
  - Providing tracking to optimize timing for transplant and facilitating real time communication about organ status
  - Promoting an electronic solution to ensure right organ/right recipient and other verifications
  - Producing electronic verification and documentation
5. *Promote the efficient management of the OPTN:* The project supports this goal by reducing time needed to complete required tasks related to organ management upon arrival to the transplant hospital.

## How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

Evaluation Objective 1: A primary goal of the proposal is to reduce or eliminate labeling or packaging errors. The analysis for this proposal will examine data reported to the patient safety system to determine the error and if the TransNet system was used, at least in part, for the case. For cases in which TransNet was used during the process in which the error occurred, an analysis will be done to determine what can

be done to minimize the error from occurring in the future. The analysis will be initiated 1 month after the implementation date and repeated quarterly for the first 2 years post-implementation.

Cohort: The analysis will be based on all labeling and packaging errors reported to the patient safety system.

Evaluation Objective 2: One of the goals of this proposal is to ensure that the TransNet system is used for all deceased donor labeling and packaging and to transmit case data on recovered organs to allow for web-based tracking in transit. The evaluation of this proposal will assess whether an OPO is using the TransNet system throughout the donor case. The analysis will be initiated 3 months after the implementation date and repeated quarterly for the first 2 years post-implementation.

Cohort: The analysis will be based on all actual donors that an OPO recovers after the policy implementation date. For each actual donor, the percent of actual donors for which TransNet was used will be calculated at the following time points:

- Case creation – A case was created in the TransNet system.
- Used in OR – A clamp date and time was entered into the system.
- Shipping of organs – Items were scanned into the shipping container and the final bar code for at least one organ was scanned to indicate the organ was ready to ship.

## How will the OPTN implement this proposal?

The OPTN will implement this proposal on June 1, 2017. This will allow ample time to prepare. The proposal will be implemented in the following ways:

IT will continue to provide user support including programming enhancements for the OPO version of TransNet. For the month prior to implementation and for the first quarter following implementation, IT plans to provide 24-7 user support. After this period, the need for 24-7 support will be reevaluated. The base functionality exists currently. OPOs started using TransNet under a voluntary nationwide deployment in March 2015. The Operations and Safety Committee has reviewed programming needs to determine and prioritize OPO functionality. Programming for OPO ability to produce VCA and multi-organ labels using TransNet is planned. IT programming for this functionality will need to be done to implement the policy without specific exemptions for these two labels. Part of the hours estimated will cover building this functionality. This proposal will not require programming in UNet<sup>SM</sup>.

Some OPOs have not yet signed up for training. If this proposal passes, the OPTN will need to reach out and ensure these OPOs sign up for training.

The Operations and Safety Committee will review rates of TransNet usage by individual OPOs. If the Committee identifies an OPO that is routinely not using the TransNet system for packaging and labeling organs or tissue typing materials, the Committee will work with the TransNet team and the OPO to assist with removing barriers that are inhibiting use. As a last resort, the OSC may refer repeated and intentional non-usage to the Membership and Professional Standards Committee (MPSC) for further review.

The project has already received extensive publicity through OPTN news releases, Transplant Pro communications, regional meetings, and professional organization meetings. The infrastructure for training and support has been established during the voluntary nationwide deployment. While additional training may be needed, the training has already been developed and evaluations have shown it to be very effective.

## How will members implement this proposal?

OPOs will need to purchase equipment necessary to label deceased donor organs using TransNet. The proposed policy would not require use of TransNet for labeling pre-recovery specimens that do not accompany the organ. A tablet and portable printer are required. Each set costs approximately \$1,000.

OPOs will need to determine how many sets they will need to provide coverage for labeling and packaging organs in the donation service area (DSA) using TransNet.

OPOs using TransNet under the voluntary launch have found various ways to employ cost efficiencies. Some OPOs have set up various ways to share equipment among staff members to minimize the number of units needing to be purchased and costs. Some OPOs have been able to use existing devices within their organization. The OSC will promote sharing lessons learned and other effective practices among all OPOs so that the early knowledge gained can benefit all OPOs.

OPOs who have not completed OPTN training will want to complete train-the-trainer instruction and pass the required competency testing. Then they should administer both training and field competency training to their own OPO staff who label and package organs.

OPOs will need to modify their internal protocols to incorporate TransNet into their labeling and packaging procedures. OPOs will also need to identify and test a back-up system in the event they cannot use TransNet temporarily. 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: Organ and Vessel Packaging, Labeling, Shipping, and Storage* and the host OPO must document the reasons the OPTN organ tracking system was not used.

OPOs will need to print a donor ID band and scan the donor ID band at the beginning of each case. They will also need to label the waterproof container that holds the documentation accompanying the organ. Policy does not currently require this label.

OPOs will need to 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. OPOs will need to scan the final shipping label and submit the case information to the OPTN Contractor using internet connectivity to enable tracking in transit. Internet connectivity is not required to utilize the TransNet system. It is only required to download the donor information from DonorNet and upload the information to the OPTN contractor.

### Will this proposal require members to submit additional data?

The proposal does not require that new data be collected but it will mean that data will have to be entered through the TransNet system and submitted to the OPTN, which is a new requirement.

TransNet will require data currently being handwritten or printed at the OPO level for labels to be entered and submitted to the OPTN through the application. In many cases, the actual data entry burden will be reduced because key required fields will only be entered one time.

TransNet use will require that OPOs validate basic donor information: donor ID, ABO, and date of birth. These data can be downloaded directly from DonorNet or hand entered. The data must be validated either on-site or remotely by a second individual. Infectious disease testing results also can be hand entered or downloaded from DonorNet. These results will also require a second person validation. TransNet users will need to indicate through check boxes in the application which organs are being recovered. Labels for documentation accompanying the organ will be a new requirement; however, the data required for this label will already have been entered for other required labels. TransNet users will also be required to scan all items that will be shipped. This is a new required process and it will produce a manifest of items being sent to the transplant hospital. See **Appendix A** for a list of TransNet labels and data fields.

One of the goals of the OPTN Principles of Data Collection is to improve patient outcomes. TransNet data collection supports this goal because it will provide the OPTN data to determine if institutional members are complying with policies and ensure patient safety when no alternative sources of data exist. Currently

the OPTN does not have a means to collect labeling, packaging, and shipping data. The data on true safety situations and errors are suspected but not completely known or documented. The system will improve how these data are generated and communicated across the transplant community. Because the data will be stored in a central place, it will enable further analyses of factors impacting patient outcomes. Real-time data on cross clamp, ice time, and transport time can be examined in relation to cold ischemia time and outcomes.

## How will members be evaluated for compliance with this proposal?

Members will be expected to comply with requirements in the proposed language. However, the proposed language will not change the current routine monitoring of OPTN members. Members may be subject to OPTN review, and are required to provide documentation as requested.

If a packaging or labeling error is reported through the OPTN Improving Patient Safety Portal, OPTN Contractor staff might verify whether the TransNet system was used by the OPO during the packaging and labeling process.



## Policy or Bylaw Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

1 **RESOLVED**, that changes to Policies 1.2 Definitions, 2.2 OPO Responsibilities, 16.1 Organs  
2 Recovered by Living Donor Recovery Hospitals, 16.2 Packaging and Labeling Responsibilities,  
3 16.3 Packaging and Labeling, 16.3.B Internal Labeling of Organs, 16.3.C Internal Labeling of  
4 Blood and Tissue Typing Materials, 16.3.D Internal Labeling of Vessels, 16.3.E.ii Mechanical  
5 Preservation Machine, 16.3.F External Labeling, 16.4.A Organ Packaging Documentation  
6 Requirements, and 16.5 Verification and Recording of Information before Shipping, as set forth  
7 below, are hereby approved, effective June 1, 2017.

### 8 **1.2 Definitions**

#### 9 **OPTN organ tracking system**

10 A software application developed and distributed by the OPTN Contractor that uses barcode technology  
11 to generate printed labels for organ packaging and tracking.  
12

### 13 **2.2 OPO Responsibilities**

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

- 15
- 16 1. Identifying potential deceased donors.
- 17 2. Providing evidence of authorization for donation.
- 18 3. Evaluating deceased donors.
- 19 4. Maintaining documentation used to exclude any patient from the imminent neurological death data
- 20 definition or the eligible data definition.
- 21 5. Verifying that death is pronounced according to applicable laws.
- 22 6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic
- 23 populations.
- 24 7. Clinical management of the deceased donor.
- 25 8. Assuring that the necessary tissue-typing material is procured, divided, and packaged.
- 26 9. Assessing deceased donor organ quality.
- 27 10. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be  
28 completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel*  
29 *Packaging, Labeling, Shipping, and Storage.*
- 30 11. Executing the match run and using the resulting match for each deceased donor organ allocation.  
31 The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs  
32 according to *Policy 12.2: VCA Allocation*.
- 33 12. Documenting and maintaining complete deceased donor information for seven years for all organs  
34 procured.
- 35 13. Ensuring that documentation for *all* of the following deceased donor information is submitted to the  
36 OPTN Contractor upon receipt to enable complete and accurate evaluation of donor suitability by  
37 transplant programs:
  - 38 a. ABO source documentation
  - 39 b. ABO subtype source documentation
  - 40 c. Infectious disease results source documentation
  - 41 d. Death pronouncement source documentation
  - 42 e. Authorization for donation source documentation
  - 43 f. Human leukocyte antigen (HLA) type
  - 44 g. Donor evaluation and management
  - 45 h. Donor medical and behavioral history
  - 46 i. Organ intraoperative findings
- 47 14. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available,

48 for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these  
49 samples are available for retrospective testing. The host OPO must document the type of sample in  
50 the deceased donor medical record and, if possible, should use qualified specimens.  
51

## 52 **16.1 Organs Recovered by Packaging and Labeling** 53 **Requirements for Living Donor Recovery Hospitals Organs** 54 **and Vessels**

55 Living donor recovery hospitals ~~must follow all of the requirements~~ are responsible for packaging,  
56 labeling, and transporting living donor organs, tissue typing material, and vessels, and tissue typing  
57 samples according to this Policy 16, with these differences:  
58

- 59 ~~1. While OPOs are responsible for packaging, labeling, and transporting deceased donor~~  
60 ~~organs, vessels, and tissue typing samples, recovery hospitals are responsible for packaging,~~  
61 ~~labeling, and transporting living donor organs, vessels, and tissue typing samples.~~  
62 1. Members are not required to use the OPTN organ tracking system for labeling and packaging  
63 living donor organs, vessels, and tissue typing samples.  
64 2. When a member repackages a living donor organ, they are not required to notify the member that  
65 originally packaged the organ.  
66 3. In addition to the list of documents in *Policy 16.4: Documentation Accompanying the Organ or*  
67 *Vessel*, living donor organs must contain the blood type source documents, donor informed  
68 consent form, and the complete medical record of the living donor. Vessels that are shipped  
69 separately from living donor organs must include the same documents as are required for shipping  
70 living donor organs.  
71 4. Blood samples and tissue typing materials must contain the donor ID and *one* of the following  
72 ~~three~~ identifiers: donor date of birth, donor initials, or a locally assigned unique ID. Each sample  
73 must contain the donor's blood type and subtype, the type of tissue, and the date and time when  
74 the sample was obtained. The recovery hospital must document in the donor record all unique  
75 identifiers used to label blood samples and tissue typing materials.  
76 5. The recovery hospital will provide specimens for tissue typing if requested. The minimum  
77 typing materials for living donor kidneys are two ACD (yellow top) tubes per kidney.  
78

## 79 **16.2 Packaging and Labeling Responsibilities**

80 The host OPO or recovery hospital is responsible for packaging and labeling organs, tissue typing  
81 material, and vessels that travel outside the recovery facilities. The host OPO or recovery hospital  
82 must make reasonable efforts to package and label organs, tissue typing specimens, and vessels in  
83 a timely fashion.  
84

85 ~~If a transplant hospital repackages an organ for transport, it must package, label, and transport the organ~~  
86 ~~according to this Policy and immediately notify the host OPO of the repackaging.~~  
87  
88

89 The host OPO must complete labeling and packaging using the OPTN organ tracking system. The OPO  
90 must develop and comply with a written protocol for an alternative labeling and packaging process if, for  
91 any temporary reason, the OPTN organ tracking system is not used. This written protocol must fulfill all  
92 the requirements in Policy 16 and the host OPO must document the reasons the OPTN organ tracking  
93 system was not used.  
94

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

99  
100 If a transplant hospital repackages an organ for transport, it must package, label, and transport the  
101 organ according to the requirements in *Policy 16*, except that the use of the OPTN organ tracking system  
102 is not required. The transplant hospital must immediately notify the host OPO of the repackaging.  
103

## 104 **16.3 Packaging and Labeling**

105  
106 The host OPO must package all organs, tissue typing material, and vessels in a sterile environment  
107 using universal precautions.  
108

109 The packaged organs from the deceased or living donor's surgical back table are to be placed  
110 directly into the wet iced shipping container. Proper insulation and temperature controlled  
111 packaging including adequate ice or refrigeration must be used to protect the organs during  
112 transport. The host OPO may either package vessels with or separate from organs.  
113

114 The transplant ~~hospital center~~ or OPO must use both internal and external transport containers  
115 to package a deceased or living donor organ that travels outside of the facility where the organ is  
116 recovered.  
117

### 118 **16.3.B Internal Labeling of Organs**

119  
120 The host OPO must securely attach the completed OPTN internal label, identifying the specific  
121 contents, to the outer-most layer of the triple sterile barrier or cassette of mechanical preservation  
122 machine holding each organ. The OPTN Contractor distributes a standardized label that must be  
123 used for this purpose. The internal label must be completed using the OPTN organ tracking system.  
124 The label must include In addition to the a description of the specific contents of the package, the  
125 label information must include the donor ID, and donor blood type and blood subtype, if used for  
126 allocation.  
127

### 128 **16.3.C Internal Labeling of Blood and Tissue Typing Materials**

129  
130 Each separate specimen container of blood or tissue typing material must have a label that will  
131 remain secured to the container under normal conditions of transport. If the blood and tissue typing  
132 materials will be accompanying the organ, the internal label must be completed using the OPTN  
133 organ tracking system. The label must include the donor ID and at least *one* of the following  
134 identifiers:  
135

- 136 • Locally assigned unique ID
- 137 • Donor date of birth
- 138 • Donor initials

139  
140 Additionally each specimen should be labeled with *both* of the following:

- 141
- 142 1. The date and time the sample was procured
- 143 2. The type of tissue
- 144

145 The donor blood type and subtype, if used for allocation, should be included on tissue typing material  
146 and blood samples if known. If the donor ID or blood type is not available during the preliminary  
147 evaluation of a donor, a locally assigned unique ID and one other identifier for the transportation of  
148 initial screening specimens may be used. The OPO must document in the OPO donor record all  
149 unique identifiers used to label tissue typing specimens.  
150

### 151 **16.3.D Internal Labeling of Vessels**

152

153 The rigid container holding the vessels and the outermost layer of the triple sterile barrier must  
 154 each have a completed OPTN vessel label. The OPTN Contractor distributes standardized labels that  
 155 must be used for this purpose. The internal label on the outermost layer of the triple sterile barrier  
 156 must be completed using the OPTN organ tracking system. The labels must ~~contain~~ include *all* of the  
 157 following information according to *Table 16-1* below.  
 158

159 **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 <i>any</i> of the following:<br><ul style="list-style-type: none"> <li>● Human Immunodeficiency Virus (HIV), Hepatitis C virus (HCV), or Hepatitis B Virus (HBsAg or NAT)</li> <li>● Hepatitis B virus (HBcAb)</li> </ul> | ●                       |   |
| 9. Whether the vessels are from a donor that meets the increased risk for disease transmission criteria in the <i>U.S. Public Health Service (PHS) Guideline</i>   | ●                       | ●   |

160  
 161  
 162 **16.3.E.ii Mechanical Preservation Machine**  
 163  
 164 ~~When transporting an organ using Members may use a mechanical preservation machine, the cassette~~  
 165 ~~containing the organ must be labeled with the organ type, UNOS ID, blood type, and blood subtype if~~  
 166 ~~used for allocation. Mechanical preservation machines may be reused only if all labels from previous~~  
 167 ~~donor organs are removed to transport organs. A mechanical preservation machine may be reused only if~~  
 168 ~~it is properly cleaned and sanitized and all labels from previous donor organs are removed.~~  
 169

170 **16.3.F External Labeling**  
 171

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

176  
177 The OPTN external label must be completed using the OPTN organ tracking system. The label must  
178 ~~contain~~ include all of the following:

- 179  
180 1. The donor ID  
181 2. The sender's name and telephone number  
182 3. The donor's blood type  
183 4. The donor's subtype, if used for allocation  
184 5. A description of the specific contents of the box  
185 6. The Organ Center's telephone number  
186

#### 187 **16.4.A Organ Packaging Documentation Requirements**

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

- 190  
191 1. Blood type  
192 2. Blood subtype, if used for allocation  
193 3. Infectious disease testing results available at the time of organ packaging  
194

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

- 196  
197 • A location specifically designed for documentation  
198 • Between the inner and external transport containers  
199

200 For deceased donor organs, the host OPO must label the watertight container. This label must be  
201 completed using the OPTN organ tracking system. The label must include the donor ID, blood  
202 type, and blood subtype if used for allocation.  
203

### 204 **16.5 Verification and Recording of Information before** 205 **Shipping**

206  
207 Each OPO or recovery hospital must establish and then implement a protocol for verifying the  
208 accuracy of organ and vessel packaging labels by an individual other than the individual initially  
209 performing the labeling and documentation.

210  
211 This verification must occur after completing the required labels and documentation for organs  
212 and vessels and the host OPO or recovery hospital must document that verification.

213  
214 The host OPO must use the OPTN organ tracking system to:

- 215  
216 1. Record each item placed into the external organ package  
217 2. Report to the OPTN Contractor that the package is ready for tracking  
218

219 #

**Appendix A: TransNet Labels and Data Fields**

| <b>Donor ID Band</b> | <b>Misc Label 1</b> | <b>Misc Label 2</b> | <b>Blood Label</b> | <b>Culture Label</b> | <b>Documentation</b> | <b>Biopsy</b>        | <b>Nodes/ Spleen/ Nodes and Spleen</b> | <b>Organ Label</b>    | <b>Shipping Label 1</b> | <b>Shipping label 2 (contents of the box)</b> | <b>Shipping Label 3</b> | <b>Shipping Label 4</b> |
|----------------------|---------------------|---------------------|--------------------|----------------------|----------------------|----------------------|--|-----------------------|-------------------------|---|-------------------------|-------------------------|
| Donor ID             | Donor ID            | Donor ID            | Donor ID           | Donor ID             | Donor ID             | Donor ID             | Donor ID                               | Donor ID              | Donor ID                | Organ   | Ice date/time 1         | Organ                   |
| DOB                  | ABO                 | ABO                 | DOB                | DOB                  | ABO                  | ABO                  | ABO                                    | ABO                   | Donor ABO               | Vessels                                       | Ice date/time 2         | Donor ID                |
| Donor Initials       | Comments            | Date                | Donor Initials     | Donor Initials       |                      | DOB                  | DOB                                    | Cross clamp date/time | Cross clamp date/time   | Documentation                                 | Originating OPO         | OPO                     |
| Local ID             |                     | Donor Hospital      | Local ID           | Local ID             |                      | Local ID             | Donor Initials                         |                       | Organ type              | Other   |                         |                         |
|                      |                     |                     | ABO                | ABO                  |                      | Collection date/time | Local ID                               |                       |                         | Blood   |                         |                         |
|                      |                     |                     | Draw date/time     | Draw date/time       |                      | Collected by         | Collection date/time                   |                       |                         | Spleen  |                         |                         |
|                      |                     |                     | Drawn by           | Drawn by             |                      | Biopsy type          | Collected by                           |                       |                         | Nodes   |                         |                         |
|                      |                     |                     | Comments           | Culture Site         |                      |                      |  |                       |                         | Biopsy  |                         |                         |
|                      |                     |                     |                    | Culture type         |                      |                      |  |                       |                         |   |                         |                         |