

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, 35 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.

This effort started in 2012 as a Health Resources and Services Administration (HRSA) project awarded funding through the U.S. Health and Human Services (HHS) Innovations program. It was one of four HHS programs intended to drive innovation in the government and healthcare. The project goals were to reduce incorrect transplantation, minimize transport errors, accelerate organ information transfer, and capture organ procurement/transport data.

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, wrong patient transplant, or organ wastage.

## Is the sponsoring Committee requesting specific feedback or input about the proposal?

The Operations and Safety Committee plans to propose an implementation date of June 2017. The Committee wants to give OPOs sufficient time to budget, purchase needed equipment, and train staff. The Committee is seeking feedback on whether this proposed implementation date will allow adequate time for preparation. More information about planned implementation is in this document.

# 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. Among voluntary reports received from 2006 to 2011, labeling and packaging/shipping errors comprised 42.6% of all reports received. Between 2012 and June 2015, labeling errors accounted for 11% and packaging/ shipping errors made up an additional 11% of all voluntary safety reports. During the same period, there were 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 packaged and labeled incorrectly. There have been cases where 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. The full FMECA report is available upon request.

In addition to labeling and packaging issues, 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 organ(s) being shipped 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. In addition, over a quarter 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 is done 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 has been implemented, 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 33 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 packaging and labeling 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 December 18, 2015, <http://optn.transplant.hrsa.gov/news/new-data-shows-kidney-allocation-system-continues-to-achieve-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 November 2015, 35 out of 58 (60%) OPOs have completed the three-day required training at UNOS headquarters including passing a proficiency test. An additional six OPOs have signed up for future training dates. A west coast training to reach OPOs who may have travel barriers is planned for April 2016.

The training has been successful. Attendee evaluations gave the training high marks to prepare them to implement the system. Out of seven trainings conducted between March 2015 and November 2015, 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.

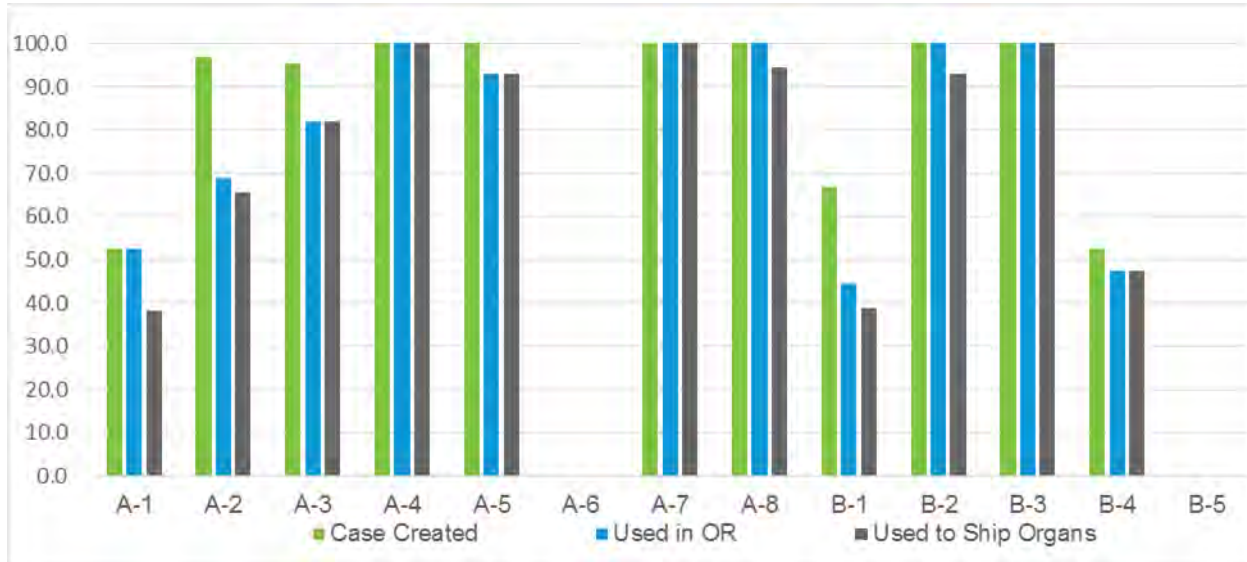
**Table 1: TransNet Training Evaluation Scores**

Skill	Before the event, please rate your ability to:	After the event, please rate your 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	2.4	4.7	+2.3

Use of TransNet continues to grow. A voluntary nationwide deployment started in March 2015 following pilot and beta testing. From September 18, 2014 – December 16, 2015, TransNet was used to package 6,947 organs from 2,029 deceased donors. A study of individual OPO usage showed that a TransNet case was created for 72.4% of all deceased donors recovered during October 2015 by the 28 trained OPOs. Fourteen OPOs (50.0%) 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.

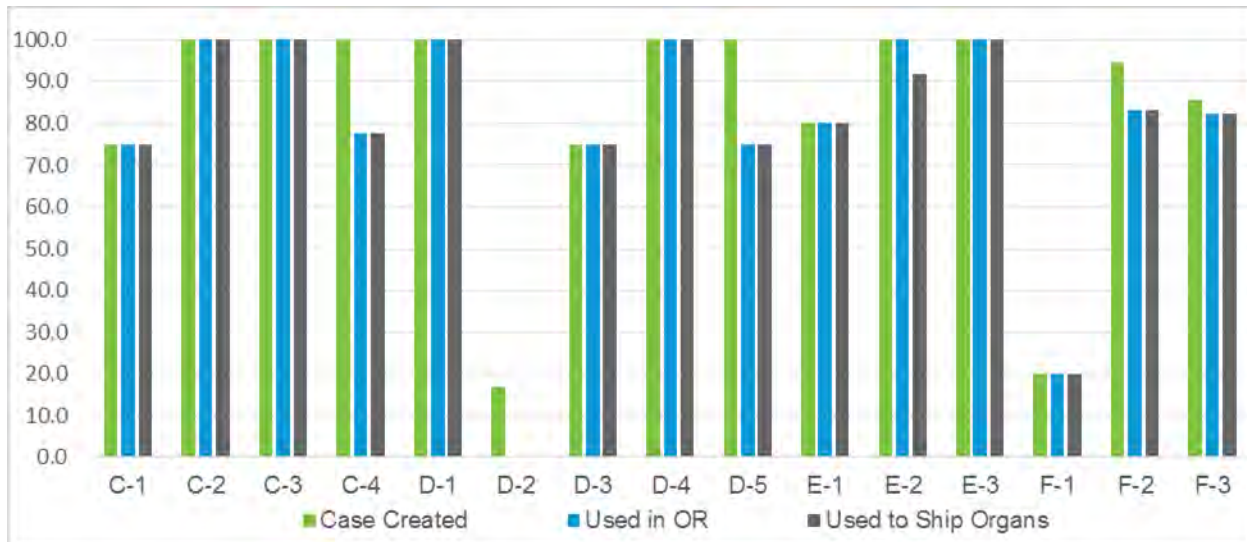
**Figures 1 and 2** show individual OPO TransNet usage for deceased donors recovered in October 2015. Of the 28 OPOs trained between September 2014 and July 2015, the majority used TransNet to create at least 80% of their cases.

**Figure 1. TransNet Usage for Deceased Donors Recovered in October 2015 by OPO- Percent of Actual Donor Cases (OPOs Trained September 2014 – July 2015), Training Groups A-B**



A-1 - A-8: OPOs in the September 2014 Training, B-1 – B5: OPOs in the March 2015 Training

**Figure 2. TransNet Usage for Deceased Donors Recovered in October 2015 by OPO- Percent of Actual Donor Cases (OPOs Trained September 2014 – July 2015), Training Groups C-F**



C-1 – C-4: OPOs in the April 2015 Training, D-1 – D-5: OPOs in the May 2015 Training

E-1 – E-3: OPOs in the June 2015 Training, F-1 – F3: OPOs in the July 2015 Training

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 has now agreed to host a training on the west coast in 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.

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 no sooner than June 2016. In March 2016, functionality will be released that will enable 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:

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

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



- 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. The Ad Hoc committee and the HRSA Innovations Fellow employed “lean” methodology as they conducted intense discovery visits with over a dozen OPOs and transplant hospitals. 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 was found to decrease risks identified with six of ten key identified processes. See **Table 2**.

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

Process Description
Complete packaging*
Generate OPTN number
Enter preliminary crossmatch results in DonorNet
Enter HLA results into DonorNet
Enter second ABO result into DonorNet
Record clamp time*
Package/label lymph nodes traveling with organ*
Print non-standard labels (for internal standard labels)*
Apply internal standard label*
Handwrite on external label*

\*Impacted by new technology

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**

<b>New functionality and process gained with application</b>	
<b>1. New functionality and process: 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. New functionality and process: 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.
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. New functionality and process: 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. New functionality and process: Donor identification with ID band with scanning capability</b>	
<i>New detective and preventive process controls gained</i>	<i>New potential failure introduced</i>

<b>New functionality and process gained with application</b>	
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. New functionality and process: “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, although 11% disagreed with the statement. 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 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

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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>.

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 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>.

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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.

<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/>.

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.

## 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 2014, there were a total of 8,596 deceased donors (60% of all donors). That same year there were 23,715 transplants using deceased donor organs. These figures are based on OPTN data as of December 4, 2015. 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?

Goal 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.

Goal 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 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. No new programming would be needed although technical support and maintenance would be required. Existing funding will cover enhancements through spring 2016. The Operations and Safety Committee has reviewed programming needs to determine and prioritize OPO functionality. Enhancements will also continue to be developed for programming within allotted resources. This proposal will not require programming in UNet<sup>SM</sup>.

The training intentions of several OPOs are uncertain at this time with one OPO indicating that they do not plan to attend training. If this proposal passes, the OPTN will need to develop a plan for training these OPOs.

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 need to complete train-the-trainer 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.

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 be labeled.

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?

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 **Exhibit A** for a list of TransNet labels and data fields.

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.

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 may 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 and (example) and language that is proposed for removal is struck through (example).

### 1.2 Definitions

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

A software application developed and distributed by the OPTN Contractor that operates on a hardware platform and 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. Reporting to the OPTN Contractor all deceased donor information required for organ placement, including the donor's human leukocyte antigen (HLA) type.
12. 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.*
13. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
14. Ensuring that written documentation of the deceased donor evaluation, donor management, authorization for donation, death pronouncement, and organ procurement quality accompanies the organ as described in *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage.*
15. 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



38 samples are available for retrospective testing. The host OPO must document the type of sample in  
39 the deceased donor medical record and, if possible, should use qualified specimens.

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## 42 **16.1 Organs Recovered by Living Donor Recovery Hospitals**

43

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

47

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

51 12. When a member repackages a living donor organ, they are not required to notify the member  
52 that originally packaged the organ.

53 23. Instead of the list of documents in *Policy 16.4: Documentation Accompanying the Organ or Vessel*,  
54 living donor organs must contain the blood type source documents, donor informed consent form,  
55 and the complete medical record of the living donor. Vessels that are shipped separately from  
56 living donor organs must include the same documents as are required for shipping living donor  
57 organs.

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

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

65 56. The recovery hospital is not required to use the OPTN organ tracking system for labeling  
66 and packaging living donor organs.

67

## 68 **16.2 Packaging and Labeling Responsibilities**

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

74

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

80

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

83

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

88

89 If a transplant hospital repackages an organ for transport, it must package, label, and transport the organ  
90 according to the requirements in *Policy 16* and immediately notify the host OPO of the repackaging.

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### 16.3.B Internal Labeling of Organs

The Host OPO must securely attach the completed OPTN internal label, identifying the specific contents, to the outer- most layer of the triple sterile barrier 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	●	●

This information must be included:	On the rigid container:	On the outermost layer of the triple sterile barrier:
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: <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>	●	●

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### 16.3.E.ii Mechanical Preservation Machine

When transporting an organ using a mechanical preservation machine, the host OPO must label the cassette containing the organ must be labeled with the OPTN Contractor standardized label. This label must be completed using the OPTN organ tracking system. The label must include the organ type, UNOS donor 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.

### 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

160 6. The Organ Center's telephone number

161

## 162 **16.4 Documentation Accompanying the Organ or** 163 **Vessel**

164

### 165 **16.4.A Organ Documentation**

166

167 Each external transport container holding an organ must be sent with the complete  
168 deceased or living donor record that includes *all* of the following:

169

- 170 1. Blood type source documentation
- 171 2. Blood subtype source documentation, if used for allocation
- 172 3. Infectious disease testing results
- 173 4. Medical and behavioral history information
- 174 5. Donor evaluation information
- 175 6. Donor authorization form
- 176 7. Organ quality information as noted in *Policy 2.15.C: Organ Procurement Procedures*

177 Donor documentation must be placed in a watertight container in *either* of the  
178 following:

179

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

182

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

186

187 When a deceased or living donor organ is transported, the host OPO or the transplant  
188 hospital must include the source documentation with the donor documentation.

189

## 190 **16.5 Verification and Recording of Information before** 191 **Shipping**

192

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

196

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

199

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

201

- 202 1. Record each item placed into the external organ package
- 203 2. Document to the OPTN Contractor that the package is ready for tracking

204

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Exhibit A

Donor ID Band	Misc Label 1	Misc Label 2	Blood Label	Culture Label	Documentation	Biopsy	Nodes/ Spleen/ Nodes and Spleen	Organ Label	Shipping Label 1	Shipping label 2 (contents of the box)	Shipping Label 3	Shipping Label 4
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								