

At-a-Glance

Proposal to Modify the Sterile Internal Vessels Label

- **Affected/Proposed Policies:** 16.4.D (Internal Labeling of Vessels)

- **Operations and Safety Committee**

This proposal seeks to modify the requirements for the sterile internal vessels label. The amount of information required on this label will be reduced. Currently all infectious disease results are required by policy to be handwritten on a “2 x 4” or “2 x 5” label in a sterile field. This process is difficult for OPOs to complete and prone to transcription errors. Infectious disease results on this label will be reduced to whether the donor is positive for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), or Hepatitis C Virus (HCV) and whether the donor is at increased risk in accordance with US Public Health Service Guidelines for HIV, HBV, or HCV. Requirements for the hangtag poly-plastic internal label attached to the outermost layer of the triple sterile barrier will not change and all infectious disease results still must be completed on this label.

- **Affected Groups**

Directors of Organ Procurement
OPO Executive Directors
OPO Medical Directors
OPO Coordinators
Transplant Administrators
Transplant Coordinators
Transplant Physicians/Surgeons
Transplant Program Directors

- **Number of Potential Candidates Affected**

This proposed policy change will not directly impact any potential candidates

- **Compliance with OPTN Strategic Goals and Final Rule**

This proposal supports the following strategic plan goals:

1. Promote transplant patient safety: Safety will be improved by reducing the chance for errors on the sterile internal vessels label and subsequently this will reduce the chance for unintended disease transmission
2. Promote efficient management of the OPTN: The current burden associated with completing this label will be reduced

- **Specific Requests for Comment**

The Committee is seeking feedback on whether the positive indication for HBV should be for any positive HBV testing result or solely for HBsAg positive results as storage of these vessels is prohibited by policy.

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Affected/Proposed Policies:

16.4.D (Internal Labeling of Vessels)

Operations and Safety Committee

Public Comment Response Period: January 27, 2015-March 27, 2015

Summary and Goals of the Proposal:

This proposal seeks to modify the requirements for the sterile internal vessels label. The amount of information required on this label will be reduced. Currently all infectious disease results are required by policy to be handwritten on a “2 x 4” or “2 x 5” label in a sterile field. This process is difficult for OPOs to complete and prone to transcription errors. Infectious disease results on this label will be reduced to whether the donor is positive for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), or Hepatitis C Virus (HCV) and whether the donor is at increased risk in accordance with US Public Health Service Guidelines for HIV, HBV, or HCV. Requirements for the hangtag poly-plastic internal label attached to the outermost layer of the triple sterile barrier will not change and all infectious disease results still must be completed on this label.

Background and Significance of the Proposal:

This proposal originated following a recommendation to the Operations and Safety Committee (OSC) from the Ad Hoc Organ Tracking Committee (OTC) In June 2013. The OTC spearheaded the original efforts of the Electronic Tracking and Transport (ETT) project. During discovery on-site visits at OPOs and subsequent organ recovery observations, it was noted that completing the sterile internal vessels label was problematic. Frequently, the labels had to be redone due to errors. In addition, a Failure Modes Effects and Criticality Analysis conducted in the initial phase of the ETT project identified labeling and packaging of vessels as the second highest failure mode. Having accurate labeling is critical for promoting patient safety and avoiding accidental transmission of infectious disease.

Following review of the recommendation, the Operations and Safety Committee initiated a project to further define the problem and develop possible solutions. The project was approved in November 2013 by the OPTN/UNOS Policy Oversight and Executive Committees. A subgroup of the OSC ETT Subcommittee was formed to work on the issue.

Collaboration:

The subgroup contained OSC representatives from both OPO and transplant hospital perspectives. An OPO Committee representative participated in the subgroup as this committee typically approves all OPTN labels. The subgroup met eight times following project approval to discuss issues with vessels labeling and develop possible solutions.

History of Policy:

Required use of the sterile internal vessels label containing all infectious disease results has a relatively short history. Use of OPTN standardized internal labels went into effect in January 2011 and included use on vessels packages. This policy also required that vessels must be packaged in a triple sterile barrier with the first layer required to be a sterile rigid container. In February 2012,

policy went into effect clarifying that the standardized OPTN labels must be on both sterile rigid container and outmost layer of triple sterile barrier.

Alternatives considered:

Several alternatives were considered during the process and these are outlined in Table 1 below.

Table 1: Alternatives Considered for Sterile Internal Vessels Labeling

Options considered but not recommended	Rationale and discussion themes
Change rigid sterile container label to identifying info only	<ul style="list-style-type: none"> • Option to include only Donor ID, ABO, recovery date and omit any infectious disease results • Less writing but maintains identification for safety purposes • Reduces chance of error for discrepant results between sterile label and hangtag poly-plastic label • Concerns if hangtag poly-plastic label gets lost during transplant process that the sterile label will not contain sufficient information for relabeling. • Concerns if the vessels are not stored in the triple sterile barrier and are needed in an emergency that the sterile label will not contain needed information. The transplant team may not have time to access DonorNet for source documentation information. • Consensus that the sterile label does not qualify as source documentation for infectious disease results, but has been used in emergencies
Package all vessels separately	<ul style="list-style-type: none"> • If all vessels were packaged separately, then they would be less likely to be unpackaged unless used. This would reduce necessity for repackaging and possible errors. • Repackaging identified as an area of risk and limited transplant hospital experience • Concerns that organs may be shipped accidentally without vessels causing unavailability at surgery • Concerns regarding the additional OPO time and packaging burden if this were adopted
Eliminate rigid sterile internal container label	<ul style="list-style-type: none"> • No sterile internal label on rigid container would reduce OPO burden of completion significantly • The hangtag poly-plastic label would be sole identification source • Concerns that a label is needed on sterile rigid container to reduce risk of inability to identify vessels if hangtag poly-plastic label becomes separated or lost during transplant • Concerns that storage in triple sterile barrier is required by policy but may not always be done due to lack of transplant hospital experience in repackaging. Vessels may accidentally be stored without identification.
No changes to sterile internal label	<ul style="list-style-type: none"> • Consensus reached that due to risk for discordant results, labeling errors, and difficulty of completion that some modifications are needed

Options considered but not recommended	Rationale and discussion themes
Discard vessels if unpackaged in operating room. Only store extra vessels that remain intact in triple sterile barrier.	<ul style="list-style-type: none"> • Option would reduce risk for separation of sterile and hangtag poly-plastic label • Difficulties in educating operating room staff OR staff and training in proper repackaging acknowledged • Concerns regarding potential vessels shortage if vessels cannot be repackaged

The Committee selected an option that reduces the number of infectious disease and risk result data fields from the 20 currently required down to two. This sterile internal vessels label will reflect two important data fields: Whether the vessels are from a donor that is at increased risk for HIV, HBV, or HCV according to the US Public Health Service Guidelines and whether the vessels are from a donor with positive results for HIV, HBV, or HCV. The small sterile internal label retains some critical information, yet will be less prone to error due to the reduction in required fields. Should the sterile and hangtag polyplastic labels become separated then the sterile label will contain identifying information and two critical pieces of information regarding HIV, HBV, or HCV status. This label will also contain a message to check source documents.

Strengths and weaknesses:

This proposal reduces chances of data transcription errors and discordant results between the sterile internal and hangtag poly-plastic internal labels. In addition, the difficulty and burden associated with completion of a small handwritten label within a sterile field will be reduced. TransNet (ETT project) will bring increased accuracy to the hangtag poly-plastic internal vessels label. It is anticipated that TransNet will be available for voluntary national deployment in March 2015. Infectious disease results can be downloaded directly from DonorNet with the most current results available. Results will be printed thereby decreasing manual transcription error. TransNet will not help with the sterile internal vessels label, as it cannot be printed on demand and meet sterility requirements.

Transplant representatives have expressed some concerns that the hangtag poly-plastic label may be lost or separated and the sterile internal label sometimes serves as the primary source of identification. Transplant hospital operating room staff often do not have access to DonorNet to check source documents to ensure complete and up to date infectious disease results for this label. Keeping some, but not all, infectious disease information on the sterile internal vessels label was agreed upon to help alleviate this concern as well as serve as a prompt to the transplant hospital personnel regarding serology results. Transplant hospitals have expressed reservations about repackaging because it is not a currently widely used or developed skill set. Educational materials are being developed for operating room staff on the proper handling and labeling of vessels in numerous situations. Effective practices, such as having repackaging kits on hand, will also be shared.

Intended and unintended consequences:

The intended consequence is a reduction in errors on the sterile internal vessels label and strengthening of practice to avoid unintentional transplantation of vessels infected with agents that could harm recipients.

The unintended consequence could be that needed infectious disease information is not available during an emergency if vessels have not been properly repackaged. The Committee will continue

monitoring patient safety situation reports and accidental disease transmission with assistance from the Ad Hoc Disease Transmission Advisory Committee (DTAC).

The current and proposed sterile internal vessels label is pictured below. On the proposed label, the “Yes” box would be checked if *any* result is positive for HIV, HBV, or HCV and this would be the cue to check the source documents for specifics. The “No” box would be checked only if all HIV, HBV, and HCV results are available and negative. The “Pending” box would be checked if all available results are negative, but some results (e.g. NAT) have not been received at the time of packaging and release.

Sterile Internal Vessels Label (Actual Size) 2” x 4”

Current

Proposed

Supporting Evidence/Modeling:

1. *Risks have been identified with current sterile internal vessels label requirements:*

Failure Modes Effects and Criticality Analysis

A 2013 Failure Modes Effects and Criticality Analysis revealed multiple potential failures in the labeling and identification processes used during deceased donor organ procurement¹. “Vessels packaged/labeled incorrectly or label incomplete” was ranked as the second highest potential failure (based on severity of risk, occurrence, and detectability) out of 146 unique vulnerabilities

¹ Holl, J. et al. Redesigning Transplant Organ Labeling UNOS Final Report. Northwestern University Feinberg School of Medicine. Center for Healthcare Studies. May 2013.

or failures resulting from 60 process steps. There is risk of infection if vessels from an increased risk or positive donor are labeled inaccurately and then used in a secondary recipient (not the recipient for whom the organ and vessels were recovered).

Reported Patient Safety Situations Related to Extra Vessels

Table 1 shows that from March 2006–June 2014, 13 reported safety situation events involved problems with the packaging and/or labeling of extra vessels, with nine of these events occurring post-implementation of the sterile rigid container label requirement.

**Table 1: Patient Safety Situations Related to Extra Vessel Packaging or Labeling Errors
March 2006 – June 2014**

Era	Date (MON-YY)	Safety Situation Description
Pre-policy requiring standardized label on outermost triple sterile barrier	Nov-08	No Serologies on vessel label
	May-09	Iliac vessel packaging error: both veins packaged for pancreas, both arteries for liver. Pancreas requires both artery and vein.
	May-10	Vessel container did not have the appropriate label.
Pre-policy requiring label on sterile rigid container	Nov-11	HCV erroneously marked as positive on vessel label.
Post-policy changes for standardized label and labels on both sterile rigid container and outermost triple sterile barrier	Aug-12	Transcription error of donor ID on sterile rigid container label (Computer printed label not possible due to sterility requirement).
	Mar-13	Vessels packaged improperly by one transplant center when sharing with another center (vessels were labeled appropriately).
	Jul-13	Missing outer hangtag vessel label. This label was actually attached to the liver bag along with the liver label. Vessels packaged only in double-bag, not required triple sterile barrier.
	Oct-13	Missing outer hangtag vessel label.
	Jan-13	Vessels repackaged improperly (only one donor identifier).
	Feb-13	Stored vessels discarded due to improper packaging, storage, or temperature related issues.
	Apr-13	Improper packaging of vessels (no cooler or ice) shared by one transplant center to another.
	May-14	EBNA test result marked negative on sterile rigid container label; however, results were pending at time of recovery, and final test result was positive.
Jun-14	Sterile rigid container label missing required information (donor ID only).	

Member Compliance

Since 2008, the vast majority of vessels were sent with livers (83%), with pancreata a distant second. Between June 1, 2012 and June 30, 2013, 47 liver programs were audited on-site for compliance with Policy 16.4.D and had vessels in their current inventory. Five programs were found to have non-compliances, resulting in an 89% compliance rate. Of these five non-compliances, four were situations where the internal hangtag poly-plastic label attached to the outermost of the three sterile barriers was missing. In one case, the sterile rigid vessel container was missing a sterile internal label.

Patient safety situation reporting is voluntary and therefore likely to be underreported. Increases in patient safety situation reporting have been increasing in general since 2006. It is difficult to draw conclusions in the actual trends except that issues with extra vessels labeling continue to be

reported and therefore are still occurring. Data from site surveys are limited by the fact that vessels must be in storage at the time of survey to be audited.

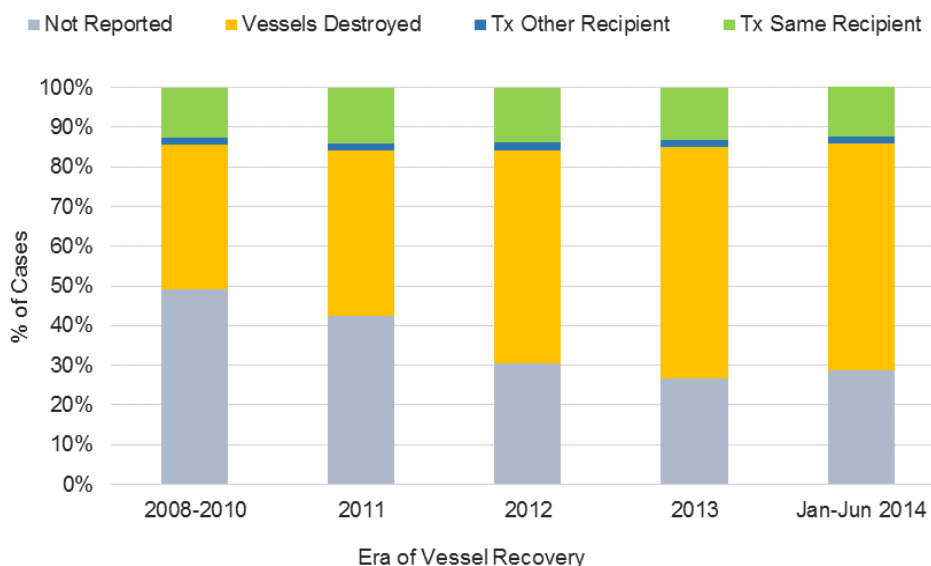
2. A significant number of vessels are recovered, however only a small percentage are used in secondary recipients. For most transplant hospitals, extra vessel use in secondary recipients is infrequent.

National Extra Vessel Disposition Reporting

From January 2008–June 2014, extra vessels were reported as having been sent for potential use in transplantation by OPOs with 46,857 organs. **Figure 1** shows that across all eras, nearly 13% of recovered extra vessels were reported as having been transplanted into the intended recipient, with about 1.7% being used in a secondary recipient. The rate of vessels reported as destroyed continues to increase, from about 36% in 2008–2010 to around 58% in 2013–June 2014. Extra vessels having a disposition of “Not Yet Reported”, has decreased considerably from nearly 50% in 2008-2010 to about 27% in 2013–June 2014.

Currently, the discard of extra vessels (as well as use of vessels in a procedure separate from the organ transplant) must be reported using the extra vessel use/destruction form. OPTN policy was approved by the OPTN Board of Directors requiring that members report disposition within seven days of the disposition in November 2012. This policy is pending implementation until an online, electronic replacement for the fax form is released in 2015. It is anticipated that compliance regarding reporting of vessel disposition will increase with the electronic process.

Figure 1: Reported Outcome of Vessels across Eras



From January 2008-June 2014, approximately 36% of all transplant hospitals (n=88) had at least one reported case of extra vessel use in a secondary recipient. Over two-thirds of these hospitals (n=63) reported between one and ten cases during this time period; 11 hospitals reported between 11-20 cases; seven hospitals reported between 21-30 cases; three reported between 31-40 cases; one reported between 41-50 cases; and three reported more than 50 cases.

The sterile internal vessels label is most significant when it becomes a primary information source due to improper storage and lack of time to consult DonorNet due to emergency surgery in a secondary recipient. The data show the opportunity for risk due to use in a secondary recipient to be most prevalent among a handful of transplant hospitals and an overall relatively infrequent occurrence.

3. *Due to increases in percentages of HCV positive and increased risk donors, some limited, but critical information should be retained on the sterile internal vessels label.*

Donor Serological and CDC High Risk/PHS Increased Risk Status

About 4% of vessels were reported recovered from hepatitis B (HBV) core antibody positive donors; about 0.1% were from hepatitis B (HBV) surface antigen positive donors; only five vessel donors have been reported as human T-lymphotropic virus type I/type II (HTLV I/II) positive since 2011. HTLV I/II testing is no longer required as of October 2009.

Since 2008, there has been a statistically significant trend in increased reports of hepatitis C (HCV) positive donors. 2.6% of reported cases in 2008–2010 were from HCV positive donors, increasing steadily to 3.9% in the first six months of 2014.

There has also been a statistically significant trend in increased reports of donors classified as Centers for Disease Control and Prevention (CDC) high risk/US Public Health Service (PHS) increased risk. Between 2008-2010, 7.9% of reported cases were from high risk donors. This percentage increased considerably across the eras to 19.5% (increased risk) in the first six months of 2014. Possible explanations for this increase could be the 2013 update to the increased risk guideline language and definitions, as well as the overall percentage of donors meeting the new definitions.

To date, there have only been two proven or probable disease transmission events involving the use of vessels in secondary recipients. Both events occurred prior to the 2012 implementation of Policy 16.7.B prohibiting storage of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels.

4. *Use of TransNet will facilitate increased accuracy of the hangtag poly-plastic label.*

TransNet will enable printing of hangtag poly-plastic labels using the most up to date infectious disease results directly downloaded from DonorNet. This will reduce risk for transcription error. It will be possible to update this label if pending results have been received post recovery and release. TransNet cannot be used to update results on the internal sterile label due to sterility issues. If the sterile internal label is not changed, this will promote discrepant results between labels. Under this proposal, there will be reduced chance of discrepant or erroneous results and therefore reduced chance of accidental use of vessels that could result in unintended disease transmission. Education efforts will focus on promoting proper repackaging and ensuring the hangtag poly-plastic label is correct if extra vessels will be stored to reduce risk of error.

Expected Impact on Living Donors or Living Donation:

Living Donors or Living Donation will not be directly impacted.

Expected Impact on Specific Patient Populations:

Specific patient populations will not be impacted.

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

This proposal supports the following strategic plan goals:

1. Promote transplant patient safety: Safety will be improved by reducing the chance for errors on the sterile internal vessels label and subsequently this will reduce the chance for unintended disease transmission
2. Promote efficient management of the OPTN: The current burden associated with completing this label will be reduced

Plan for Evaluating the Proposal:

The primary goal of this proposal is to enhance patient safety, in particular with respect to reducing disease transmission in the area of vessel recovery, storage, and transplant.

This evaluation plan is designed to track effectiveness of this proposal, which includes policy changes and member education.

The proposal will be evaluated by tracking the following:

Indicator	Evaluation Starting Time Point
Number of patient safety situation reports regarding vessel labeling*	6 months, 1 year, and 2 years post-implementation
Number of proven/probable disease transmission cases involving vessels transplanted into secondary recipients*	6 months, 1 year, and 2 years post-implementation
Reported extra vessel disposition, including donor serological and increased-risk status	6 months, 1 year, and 2 years post-implementation

* Note: Though formal evaluation of this proposal includes a review of aggregate data at 6 months and 1-year post implementation, these cases are also reviewed and followed-up by the OPTN Contractor on a real-time basis.

The committee hypothesizes that implementation of this proposal will lead to a decrease in the actual number of reported patient safety situations related to errors in vessel packaging and labeling. However, comparisons of patient safety situation reports before vs. after implementation must be interpreted cautiously, in light of the overall increasing trend observed from 2006 to 2014 in patient safety situation reporting.

Additional Data Collection:

No additional data collection will be required.

Expected Implementation Plan:

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015. If passed by the Board, the proposal would go into effect September 1, 2015.

OPOs will need to:

1. Educate staff on completion and use of the modified sterile internal vessels label
2. Replace current sterile vessels label with the modified version
3. Use the modified sterile internal vessels label starting September 1, 2015

Transplant hospitals will need to:

1. Familiarize staff with the look and information contained on the modified sterile internal vessels label

The Operations and Safety Committee is working on educational products to assist transplant hospitals and their operating room staff in proper handling of vessels including labeling, repackaging, and general vessels requirements.

Communication and Education Plan:

Communication and education regarding this proposal will be incorporated into overall education efforts related to proper handling of vessels including labeling, repackaging, and general vessels requirements. A small educational program will likely be required and the proposal will be monitored for specific instructional needs throughout the public comment and approval process.

Specific communication efforts associated with the proposal will include:

- Policy notice
- Updates to Help Documentation in UNetSM
- Transplant Pro E-newsletter article
- Presentation at Regional Meetings
- Articles/Guidance Documents on the Web

Compliance Monitoring:

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.

Policy or Bylaw Proposal:

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

16.4.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 ~~a~~ standardized labels that must be used for this purpose. The labels must contain *all* of the following information according to Table 16-1 below:

- ~~1. Donor ID~~
- ~~2. Donor blood type~~
- ~~3. Donor blood subtype, if used for allocation~~
- ~~4. Recovery date~~
- ~~5. All infectious disease testing results~~
- ~~6. Description of the container contents~~

- 7. ~~Whether the vessels are from a donor that meets the increased risk for disease transmission criteria in the U.S. Public Health Services (PHS) Guideline.~~
- 8. ~~That the vessel is for use in organ transplantation only~~

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

<u>This information must be included:</u>	<u>On the rigid container:</u>	<u>On the outermost layer of the triple sterile barrier:</u>
1. <u>Donor ID</u>	● —	● —
2. <u>Donor blood type</u>	● —	● —
3. <u>Donor blood subtype, if used for allocation</u>	● —	● —
4. <u>Recovery date</u>	● —	● —
5. <u>Description of the container contents</u>	● —	● —
6. <u>That the vessel is for use in organ transplantation only</u>	● —	● —
7. <u>Whether the vessels are from a donor that meets the increased risk for disease transmission criteria in the U.S. Public Health Service (PHS) Guideline</u>	● —	● —
8. <u>All infectious disease testing results</u>		● —
9. <u>Whether the vessels are from a donor with positive results for HIV, HBV, or HCV</u>	● —	

Appendix A: Current Internal Extra Vessels Labeling

The link to Appendix A is below.

[Appendix A: Current Internal Extra Vessels Labeling](#)