

OPTN/UNOS Policy Notice

Extra Vessels: Reducing Reporting Burdens and Clarifying Policies

Sponsoring Committee:

Policy/Bylaws Affected:

Operations and Safety Committee

1.2 (Definitions), 2.7.A (Exceptions to HIV Screening Requirement), 2.14.C (Organ Procurement Procedures), 2.14.D (Required Tissue Typing and Blood Type Verification Materials), 2.14.E (Authorization Requirement), 5.4.B (Order of Allocation), 5.5.C (OPO Requirements for Positive HIV Results), 5.8.C (Additional Pre-Transplant Verification Requirements for Extra Vessels), 5.9 (Released Organs), 9.8.A (Segmental Transplant and Allocation of Liver Segments), 14.8 (Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials), 14.8.A (Living Donor Vessel Recovery and Transplant), 14.8.B (Living Donors Vessel Storage), 15.3 (Informed Consent of Transmissible Disease Risk), 15.4.B (Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy), 16.1 (Packaging and Labeling Requirements for Living Donor Organs and Vessels), 16.2 (Packaging and Labeling Responsibilities), 16.3 (Packaging and Labeling), 16.3.A (Internal Packaging), 16.3.D (Internal Labeling of Vessels Packaged Separately from Other Organs), 16.3.E.i (Disposable Shipping Box), 16.3.E.iii (Cooler), 16.4 (Documentation Accompanying the Organ or Vessel), 16.4.A (Organ Packaging Documentation Requirements), 16.4.B (Vessel Documentation), 16.5 (Verification and Recording of Information before Shipping), 16.6 (Vessel Recovery, Transplant, and Storage), 16.6.A (Deceased Donor Vessel Recovery and Transplant Use), 16.6.B (Vessel Storage), 16.6.C (Blood Type Verification Prior to Transplant of Deceased Donor Vessels), 16.6.D (Recovery and Storage of Vessels from Living Donors), and

Public Comment:
Board Approval Date:
Effective Date:

16.6.E (Blood Type Verification Prior to Transplant of Living Donor Vessels)
January 22, 2018 – March 23, 2018
June 12, 2018
September 1, 2018, except the change to *Table 16.1: Required Information on Internal Labels for Extra Vessels, number 7* (infectious disease donor screen test results), which will be effective pending implementation and notice to OPTN members.

Problem Statement

The changes address three problem areas associated with extra vessels policies:

1. **Sharing Requirements:** Current extra vessels sharing requirements create excess reporting burden for transplant hospitals without benefit.
2. **Label Requirements:** Policy requires all infectious disease results to be noted on the extra vessels label that is attached to the outermost layer of the triple sterile barrier. But, there are too many results to fit on the current label. Additionally, DonorNetsm and the extra vessels label are out of alignment on test choices, test name labels, and test result labels. Finally, the paper label is static and might not contain the most up to date results.
3. **Policy Consistency with the Final Rule:** The OPTN Final Rule (42 CFR 121 *et seq.*) states that vessels, including those not attached to the organ (which we call “extra vessels”), are considered part of the organ with which they are procured and “shall be subject to the allocation requirements and policies pertaining to the organ with which the blood vessel is procured until and unless the transplant center receiving the organ determines that the blood vessel is not needed for the transplantation of that organ.” Some OPTN policies needed to be modified to be consistent with this principle.

Summary of Changes

1. **Sharing Requirements:** The requirements when sharing extra vessels between transplant hospitals have changed. Members no longer have to submit a justification. Sharing extra vessels must be reported to the OPTN Contractor within seven days of the action.
2. **Label Requirements:** The extra vessels label, DonorNet, and TransNet will become aligned for test name label and test result options. For example, all hepatitis B core antibody tests will read anti-HBc (versus differing terms such as HBcAb being used). Test result choices will also align with five options. The labels will contain only results for HIV, hepatitis B, and hepatitis C. Other infectious disease test results in DonorNet will be available using a barcode scan that will print with the revised TransNet label. Strongyloides will be added as an optional test in DonorNet and results will be available when using the barcode scan.
3. **Policy Consistency with the Final Rule:** Many changes involve using the term “extra vessels” versus “vessel” or “vessels”. Other changes include deleting extra vessels (or vessels) in policy because the wording is not necessary. The policy requirement still applies because extra vessels are considered part of the organ with which they were recovered. Policies applying to the organ also apply to extra vessels unless specified otherwise. In some areas, policies were clarified or amended.

Verification requirements were reduced from “all” infectious disease results in both donors and recipients to infectious disease results only in donors. Policy was clarified that informed consent is required when using PHS increased risk extra vessels in a secondary recipient. A clause was added to allow use in emergent situations with recipient notification after the procedure as well as follow up required for all recipients of PHS increased risk organs. A complete list of changes is available below in Table 1: Details on Proposed Policy Changes.

All changes will go into effect on September 1, 2018, except the changes to the extra vessels label that goes on the outermost layer of the triple sterile barrier. This is dependent on programming and revising and reprinting the physical polyplastic label. This will go into effect upon member notification.

What Members Need to Do

Transplant Hospitals

Transplant hospitals will no longer need to submit justifications to the MPSC when extra vessels are shared. Transplant hospitals that send extra vessels will now report those to the OPTN Contractor within seven days of sharing. Transplant hospitals that receive extra vessels will continue to report their use or destruction to the OPTN Contractor within seven days of their use or destruction.

For the second part of the proposal, transplant hospitals will need to become familiar with the new label and what it contains. If transplant hospitals plan to access the other infectious disease results using the bar code in TransNet, then they will have to train staff on how to do this, which will be available on the TransNet website. If transplant hospitals repackage extra vessels and make a new label, then they would need to purchase the new labels.

For the third part, transplant hospitals will need to educate staff, emphasizing that the organ requirements, such as those for infectious disease reporting, apply to extra vessels even if the word vessels is no longer in policy. Other changes, such as clarifying that informed consent is needed when using PHS increased risk extra vessels in a secondary recipient, might need staff education depending on the transplant hospital's current practices.

OPOs

OPOs will have to train staff on changed rules and changed data entry in DonorNet. If additional testing results are incorporated into DonorNet, then OPOs will need to inform data vendors to change data mining and exporting practices. OPOs will have to purchase and use the revised extra vessels labels. Data vendors might need to adjust their data files when the unknown option is eliminated as a test result option.

For the second part of the proposal, OPOs will need to purchase and use the new extra vessel labels. OPOs will need to become familiar with the new label. They will need to train staff on printing two versus three TransNet labels and the placement on the new polyplastic label.

OPOs will also need to educate staff that the organ requirements, such as those for infectious disease reporting, apply to extra vessels even if the word vessels is no longer in policy. OPOs will be given read access in TIEDI for extra vessels that they recovered to help comply and to improve post-transplant communications.

Table 1: Details on Proposed Policy Changes

| Affected Policies | Added word "extra" before "vessels" for clarification | Deleted word "vessels" Policy requirement still applies because it applies to the organ | Added an exclusion for extra vessels | Notes |
|---|--|--|---|---|
| 1.2 Definitions | | | | Revised extra vessels and organ definitions for clarity |
| 2.7.A Exceptions to HIV Screening | | | | Revised so that although extra vessels may be used with organs (except kidney) not yet screened for HIV in medical emergencies that the extra vessels must not be stored, shared, or used in another recipient prior to HIV screening results |
| 2.15.C Organ Procurement Procedures | | | Yes | Abnormalities or surgical damage to extra vessels do not have to be documented |
| 2.15.D Required Tissue Typing and Blood Type Verification Materials | | | Yes | Extra vessels procured for transplantation are excluded from minimum tissue typing material requirements. |
| 2.15.E Authorization Requirement | | | | Clarified that extra vessels may only be recovered with at least one organ. Moved deceased donor authorization language from Policy 16 to this Policy 2.15E |
| 5.4.B Order of Allocation | | | Yes | Clarified that extra vessels allocated with an organ but not required for its transplant can be shared and is not subject to other organ reallocation requirements. |
| 5.5.C OPO Requirements for Positive HIV Results | | | Yes | Clarified that extra vessels recovered with HIV positive kidneys or livers must only be used for transplantation of these organs and must not be stored. |
| 5.9 Released Organs | | | Yes | Clarified that if extra vessels are not used for the recipient, then the transplant hospital may use, share, or store extra vessels |
| 9.8.A Segmental Transplant and Allocation of Liver Segments | | Yes | | This policy appears to apply to attached vessels but might be confused with both and is ultimately not needed. |
| 14.8 Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials | Yes | Yes | | |
| 14.8.A Living Donor Extra Vessel Recovery and Transplant | Yes | | | Modified policy title |
| 14.8.B Living Donors Vessel Storage | | | | Combined 14.8.A and 14.8.B |

| Affected Policies | Added word "extra" before "vessels" for clarification | Deleted word "vessels" Policy requirement still applies because it applies to the organ | Added an exclusion for extra vessels | Notes |
|--|---|---|--------------------------------------|--|
| 15.3 Informed Consent of Transmissible Disease Risk | | | | Substantive change: Added policy requirements when extra vessels from increased risk donors must be used in an emergency and informed consent could not be obtained beforehand. After transplant, the recipient must be informed and followed with increased risk post-transplant testing. |
| 15.4.B Host OPO Requirements for Reporting Post Procurement Discovery of Recipient Disease or Malignancy | | Yes | | |
| Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage | Yes | | | |
| 16.1 Packaging and Labeling Requirements for Living Donor Organs and Vessels | Yes | Yes | | |
| 16.2 Packaging and Labeling Responsibilities | | Yes | | Deleted unenforceable language about packaging in a "timely" fashion |
| 16.3 Packaging and Labeling | Yes | Yes | | Clarified "same external transport container with the organ" |
| 16.3.A Internal Packaging | Yes | Yes | | |
| 16.3.D Internal Labeling of Vessels Packaged Separately from Other Organs | Yes | | | Substantive change: Changed label requirement from "all" infectious disease results to results for HIV, HBV, and HCV testing. |
| 16.3.E.i Disposable Shipping Box | | Yes | | |
| 16.3.E.iii Cooler | | Yes | | |
| 16.4 Documentation Accompanying the Organ or Vessel | Yes | | | |
| 16.4.A Organ Packaging Documentation Requirements | | | | |
| 16.4.B Vessel Documentation | | | | Combined 16.4.A and 16.4.B |
| 16.5 Verification and Recording of Information before Shipping | | Yes | | |
| 16.6 Vessel Recovery, Transplant, and Storage | Yes | | | |
| 16.6.A Deceased Donor Vessel Recovery and Transplant | Yes | | | Substantive change: Deleted requirement to submit justification for extra vessels sharing |

| Affected Policies | Added word "extra" before "vessels" for clarification | Deleted word "vessels" Policy requirement still applies because it applies to the organ | Added an exclusion for extra vessels | Notes |
|--|---|---|--------------------------------------|--|
| 16.6.B Vessel Storage | Yes | | | |
| 16.6.C Blood Type Verification Prior to Transplant of Deceased Donor Vessels | Yes | | | Substantive change: Changed verification requirements regarding infectious disease results from "all" to HIV, HBV, and HCV. Combined living and deceased donor policy and clarified circumstances of verification. Added allowed use of TransNet for consistency with Policy 5.8. Content moved to Policy 5.8.C to be closer to other verification policy. |
| 16.6.D Recovery and Storage of Vessels from Living Donors | | | | Substantive change: Added reporting requirement for sharing extra vessels to use and destruction requirement. Moved reporting policy out of storage section and into new reporting section for clarity. Authorization requirement unchanged but moved to Policy 14.8.A. Living donor extra vessels use requirements unchanged but moved to Policy 16.6.A. |
| 16.6.E Blood Type Verification Prior to Transplant of Living Donor Vessels | | | | Combined with 16.6.C and moved into Policy 5.8.C to be closer to other verification policy. |

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

1.2 Definitions

Extra vessels

~~A vessels taken during procurement recovery of deceased or living donor organs with the intent to be used in organ transplantation only. for vasculature reconstruction or modification of a transplanted organ. Vessels directly attached to the transplantable organ are not considered extra vessels.~~ Extra vessels are routinely taken from areas not immediately connected to the transplantable organ. Extra vessels are subject to the same member requirements applying to the organ unless otherwise specified.

Organ

A human kidney, liver, heart, lung, pancreas, intestine (including the esophagus, stomach, small or large intestine, or any portion of the gastrointestinal tract), or vascularized composite allograft. Blood vessels, including extra vessels, recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of ~~this part~~ these Policies if the vessels are intended for use in organ transplantation and labeled “For use in organ transplantation only.”

2.7.A Exceptions to HIV Screening Requirement

Exceptions to the HIV screening requirement may be made for organs *other than* kidneys, when, in the medical judgment of the host OPO and recipient transplant hospital or OPO, an extreme medical emergency warrants the transplantation of an organ that has not been tested for HIV.

In this case the host OPO must do *both* of the following:

1. Provide all available deceased donor medical and social history to the transplant program
2. Treat the deceased donor as having an increased risk for disease transmission based on the current U.S. Public Health Services (PHS) Guideline

In this case the receiving transplant hospital must:

- Obtain and document informed consent from the potential transplant recipient or the recipient’s authorized agent before transplantation
- Obtain HIV screening test results prior to storing, sharing, or using the extra vessels in another recipient, according to *Policy 16.6: Extra Vessels Transplant and Storage*

2.14.C Organ Procurement Procedures

To ensure organ procurement quality, the host OPO must do *all* of the following:

1. Ensure that the deceased donor receives medications at appropriate times
2. Document in the deceased donor record any medications administered
3. Begin tissue typing and crossmatching as soon as possible
4. Use standard surgical techniques in a sterile environment
5. Maintain flush solutions, additives, and preservation media at appropriate temperatures

Document in the deceased donor record, flush solutions and additives with lot numbers, along with organ anatomy, organ flush characteristics, flush solution amount, and flush solution type

6. Document any organ abnormalities, and surgical damage, ~~if any~~ for all organs except extra vessels

2.14.D Required Tissue Typing and Blood Type Verification Materials

The host OPO must establish a written policy with an ~~OPTN member~~ histocompatibility laboratory that includes specific details of the minimum tissue typing material, type of specimen, medium, and shipping requirements for these items. Extra vessels recovered for transplantation are excluded from minimum tissue typing material requirements. *Table 2-4* shows the minimum tissue typing material requirements for each organ ~~of this type~~.

Table 2-4: Minimum Typing Materials

| The host OPO must provide: | For this organ: |
|---|---|
| One 7 to 10 mL clot red top tube | Any organ |
| Two acid-citrate-dextrose (ACD) yellow top tubes | Kidney or pancreas |
| If available, one 2 by 4 cm wedge of spleen in culture medium | Kidney or pancreas |
| Three to five lymph node samples | <ul style="list-style-type: none"> • Each kidney or pancreas • Any organ, if the receiving transplant hospital requests and they are available- |

The host OPO will provide specimens for tissue typing for all other organs as requested.

2.14.E Deceased Donor Authorization Requirement

~~Organ recovery teams~~ The host OPO may only recover organs that ~~they have~~ it has received authorization to recover. An authorized organ should be recovered if it is transplantable or a potential transplant recipient is identified for the organ. If an authorized organ is not recovered, the host OPO must document the specific reason for non-recovery.

Extra vessels may only be recovered with at least one organ. To recover and use extra vessels in an organ transplant, the deceased donor authorization forms must include language indicating that the extra vessels will be used for transplant.

~~This policy does not apply to VCA transplants.~~ Recovery of vascularized composite allografts (VCAs) for transplant must be specifically authorized from individuals authorizing donation, whether that be the donor or a surrogate donation decision-maker consistent with applicable state law. The specific authorization for VCA must be documented by the host OPO.

5.4.B Order of Allocation

The process to allocate deceased donor organs occurs with these steps:

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential transplant recipients (PTRs) in the order that the ~~potential recipients~~ PTRs appear on a match run.

4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update candidates' data with the OPTN Contractor. The host OPO must re-execute the match run to allocate the organ.
5. If no transplant program within the DSA or through an approved regional sharing arrangement accepts the organ, the Organ Center will allocate the organ according to Policy.
6. Extra vessels allocated with an organ but not required for its transplant can be shared according to *Policy 16.6.A: Extra Vessels Use and Sharing*.
- 6.7. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all PTRs potential recipients on the match run. Members must submit the *Organ Export Verification Form* to the OPTN Contractor prior to exporting deceased donor organs.

This policy does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.

5.5.C OPO Requirements for Positive HIV Results

If a donor is found to be positive for HIV after any match run has been executed, the host OPO must report the updated information to the OPTN Contractor and do *all* of the following for each organ being allocated:

1. Stop allocation on the original match run for this donor
2. Re-execute the kidney and liver match runs in order to include *only* HIV-positive candidates participating in an institutional review board approved research protocol that meets the requirements in the Final Rule regarding the recovery of organs from individuals known to be infected with HIV according to *Policy 15.7.A: Requirements for Allocating HIV Positive Deceased Donor Organs*
3. Withdraw any pending offers to candidates who are not HIV positive *and* also participating in an institutional review board approved research protocol that meets the requirements in the OPTN Final Rule according to *Policy 15.7.C: Transplant Hospital Requirements for Transplantation of HIV Positive Organs*
4. Allocate *only* kidneys and livers from HIV positive donors. Extra vessels from these donors must only be allocated with the kidneys or liver and must only be used for transplantation of these organs. Members must not store or share extra vessels from HIV positive donors.

5.8.C Additional Pre-Transplant Verification Requirements for Extra Vessels

If any of the following occurs:

- Deceased donor extra vessels recovered with an organ will be used in the transplantation of a different organ
- Extra vessels will be used in the modification of a transplanted organ

Then, prior to transplant of the extra vessels, transplant hospitals must complete all of the following:

1. Meet the requirements according to *Policy 5.8: Pre-Transplant Verification*
2. Verify the extra vessels are within 14 days of the recovery date
3. Verify the extra vessels donor's infectious disease testing results for HIV, hepatitis B (HBV), and hepatitis C (HCV)
4. Document and maintain these verifications in the recipient medical record

5.9 Released Organs

The transplant surgeon or physician responsible for the care of a candidate will make the final decision whether to transplant the organ.

The transplant program must transplant all accepted, deceased donor organs into the originally ~~designated~~ intended recipient or release the deceased donor organs back to and notify the host OPO or the OPTN Contractor for further distribution. If a transplant program released an organ, it must explain to the OPTN Contractor the reason for refusing the organ for that candidate. The host OPO must then allocate the organ to other candidates according to the organ-specific policies. The host OPO may delegate this responsibility to the OPTN Contractor or to the OPO serving the candidate transplant program's DSA.

If extra vessels are not used for the recipient, then the transplant hospital may use, share, or store extra vessels, according to *Policy 16: Organ and Extra Vessels Packaging, Labeling, Shipping, and Storage*.

9.8.A Segmental Transplant and Allocation of Liver Segments

If a transplant program accepts a liver and performs a segmental transplant, the host OPO must make reasonable attempts to offer the remaining segment according to the adult deceased donor liver match run. If the remaining segment has not been allocated by the time the deceased donor organ procurement has started, the transplant hospital must offer it to candidates registered with the transplant program, or any medically appropriate candidate on the waiting list.

The match run will identify a donor's liver as one with the potential to be split if the donor meets *all* the following criteria:

1. Less than 40-years old
2. On a single vasopressor or less
3. Transaminases no greater than three times the normal level
4. Body mass index (BMI) of 28 or less

The deceased donor liver match run will also indicate if potential transplant recipients are willing to accept a segmental liver transplant.

If the potential transplant recipient that receives the primary whole liver offer ultimately declines the liver, any subsequent segmental allocation must be relinquished so that the host OPO may reallocate the whole liver using the liver match run that corresponds to the deceased donor's age.

The transplant hospital that receives the primary whole liver offer will determine how the liver will be split ~~and how the vessels are used~~.

14.8 Packaging, Labeling, and Transporting of Living Donor Organs, Extra Vessels, and Tissue Typing Materials

Recovery hospitals are responsible for packaging and labeling any living donor organs, or tissue typing specimens, ~~or vessels~~ that are recovered from living donors according to *Policy 16: Organ and Extra Vessels Packaging, Labeling, Shipping, and Storage* when *either* of the following occurs:

- Living donor organs, or tissue typing specimens, ~~or vessels~~ are recovered and must be transported outside the recovery hospital

- A living donor organ, or tissue typing specimens, or vessels require repackaging by a transplant hospital for transport outside the transplant hospital

14.8.A Living Donor Extra Vessels Recovery and Transplant Storage

A recovery hospital ~~may~~ must only recover extra vessels for transplant if the living donor consents to the removal of extra vessels for transplant. The extra vessels from a living donor ~~can~~ must only be used for transplant or modification of an organ transplant for the original intended recipient.

~~14.8.B Living Donors Vessel Storage~~

Any extra vessels recovered from living donors must be stored according to ~~Policy 16.7: Vessel Recovery, Transplant, and Storage~~ Policy 16.6.B: Extra Vessels Storage.

15.3 Informed Consent of Transmissible Disease Risk

Transplant programs must obtain specific informed consent before transplant of any organ when *any* of the following occurs:

- The donor has a known medical condition that may, in the transplant hospital's medical judgment, be transmissible to the recipient, including HIV.
- The donor meets any of the criteria for increased risk of transmitting HIV, hepatitis B, and hepatitis C as specified in the *U.S. Public Health Services (PHS) Guideline*.
- When a hemodiluted specimen is used for donor HIV, hepatitis B, or hepatitis C screening, according to *Policy 2.5: Hemodilution Assessment*.

Exceptions to the informed consent requirement may be made for extra vessels when, in the medical judgment of the transplanting physician, the extra vessels are required for use in an emergency transplant procedure for an organ other than the organ with which they were recovered. In this case, the transplant hospital must do *both* of the following post-transplant:

2. Inform the recipient of the use of the extra vessels and the increased risk status
3. Provide follow up to the recipient according to *Policy 15.3.B: Donors at Increased Risk for Transmission of Blood-borne Pathogens*

Transplant programs must also inform potential candidates of the general risks of potential transmission of malignancies and disease from organ donors, including *all* of the following information:

1. Deceased donors are evaluated and screened as outlined in *Policy 2.3: Evaluating and Screening Potential Deceased Donors*.
2. Living Donors are required to undergo screening for the diseases listed in *Policy 14.4: Medical Evaluation Requirements for Living Donors*.
3. That there is no comprehensive way to screen deceased and living donors for all transmissible diseases.
4. That transmissible diseases and malignancies may be identified after transplant.

The transplant program must do *both* of the following:

1. Explain these risks and obtain informed consent from the potential candidate or candidate's agent before transplant.
2. Document consent in the potential candidate's medical record.

15.4.B Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy

If the host OPO is notified that an organ recipient is suspected to have, is confirmed positive for, or dies from a potential transmissible disease, infection, or malignancy, and there is substantial concern that it could be from the transplanted organ, then the host OPO must do *all* the following:

1. Communicate the suspected donor's and affected organ recipient's test results and diagnosis that may be relevant to acute patient care, as soon as possible but no more than 24 hours after receipt, to any transplant program patient safety contacts and tissue banks that received organs, ~~vessels~~ or tissue from the donor. This includes any test results that were not available at the time of procurement or that were performed after procurement. The host OPO must document that this information is shared with all receiving transplant programs and tissue banks.
2. Report the event to the OPTN Improving Patient Safety Portal as soon as possible but no more than 24 hours after notification or receipt of recipient test results or diagnosis.

Policy 16: Organ and Extra Vessels Packaging, Labeling, Shipping, and Storage

16.1 Packaging and Labeling Requirements for Living Donor Organs and Extra Vessels

Living donor recovery hospitals are responsible for packaging, labeling, and transporting living donor organs, ~~vessels~~, and tissue typing samples according to *Policy 16*, with these differences:

1. Members are not required to use the OPTN organ tracking system for labeling and packaging living donor organs, ~~vessels~~, and tissue typing samples.
2. When a member repackages a living donor organ, ~~they are the member~~ is not required to notify the member that originally packaged the organ.
3. In addition to the list of documents in *Policy 16.4: Documentation Accompanying the Organ or Extra Vessels*, living donor organs must contain the blood type source documents, donor informed consent form, and the complete medical record of the living donor. Extra ~~vessels~~ that are shipped separately from living donor organs must include the same documents as are required for shipping living donor organs.
4. Blood samples and tissue typing materials must contain the donor ID and *one* of the following identifiers: donor date of birth, donor initials, or a locally assigned unique ID. Each sample must contain the donor's blood type and subtype, the type of tissue, and the date and time when the sample was obtained. The recovery hospital must document in the donor record all unique identifiers used to label blood samples and tissue typing materials.
5. The recovery hospital will provide specimens for tissue typing if requested. The minimum typing materials for living donor kidneys are: two ACD (yellow top) tubes per kidney.

16.2 Packaging and Labeling Responsibilities

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

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 according to in Policy 16: Organ and Extra Vessels Packaging, Labeling, Shipping, and Storage and the host OPO must document the reasons the OPTN organ tracking system was not used.

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

If a transplant hospital repackages an organ for transport, it must package, label, and transport the organ, according to ~~the requirements in~~ Policy 16: Organ and Extra Vessels Packaging, Labeling, Shipping, and Storage, except that the use of the OPTN organ tracking system is not required. The transplant hospital must immediately notify the host OPO of the repackaging.

16.3 Packaging and Labeling

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

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

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

16.3.A Internal Packaging

A triple sterile barrier must protect organs ~~and vessels~~. A rigid container must be used as one of these layers when packaging kidneys, pancreas, ~~and or~~ extra vessels that are packaged separately from the organs. If the rigid container is sterile, it can serve as one layer of the required triple sterile barrier. The use of a rigid container is optional for all other organs.

16.3.D Internal Labeling of Extra Vessels Packaged Separately from Other Organs

The rigid container holding the extra vessels and the outermost layer of the triple sterile barrier must each have a completed OPTN extra vessels 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 include *all* of the following information according to *Table 16-1* below.

Table 16-1: Required Information on Internal Labels for Extra 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 <u>extra vessels</u> is <u>are</u> for use in organ transplantation only | ● | ● |
| 7. All <u>infectious disease donor screening test results for all of the following:</u> <u>a. anti-HIV I/II</u> <u>b. HIV Ag/Ab combo</u> <u>c. HIV NAT</u> <u>d. anti-HBc</u> <u>e. HBsAg</u> <u>f. HBV NAT</u> <u>g. anti-HCV</u> <u>h. HCV NAT</u> | | ● |
| 8. Whether the <u>extra vessels</u> are from a donor with a positive result (<u>including NAT included</u>) for <u>any</u> of the following: <ul style="list-style-type: none"> • Human Immunodeficiency Virus (HIV), Hepatitis C virus (HCV), or Hepatitis B Virus HBV (HBsAg or NAT) or HCV • Hepatitis B virus (HBcAb)-anti-HBc | ● | |
| 9. Whether the <u>extra vessels</u> are from a donor that meets the <u>criteria for increased risk of transmitting HIV, hepatitis B, or hepatitis C, as specified increased risk for disease transmission criteria in the U.S. Public Health Service (PHS) Guideline</u> | ● | ● |

16.3.E.i Disposable Shipping Box

If organs, ~~or tissue typing materials,~~ ~~or vessels~~ are shipped commercially, they must be transported in a new disposable shipping box. Disposable shipping boxes may not be reused and each box must contain *all* of the following:

1. A closed plastic liner inside the insulated container to encase the cooling material. The liner must be secured and leak-proof.
2. An inner insulated container, 1.5 inches thick, or a container with an equivalent thermal resistance. The container must have proper insulation and enough cooling material to protect the organs during normal conditions of transport.

3. A water-tight, secured, colored, opaque plastic liner between the outer and inner containers. The liner must be secured and leak-proof.
4. An outer container of corrugated plastic or corrugated cardboard, with at least 200 pounds burst strength, that is coated with a water resistant substance.

16.3.E.iii Cooler

If a member of the organ recovery team is accompanying the organ to the potential transplant recipient's transplant hospital, the organs and tissue typing materials, ~~and vessels~~ may be transported in a cooler. A cooler may be reused only if it is properly cleaned and sanitized and all labels from previous donor organs are removed.

16.4 Documentation Accompanying the Organ or Extra Vessels

16.4.A Organ Packaging Documentation Requirements

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

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

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

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

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

~~16.4.B~~ Vessel Documentation

If extra vessels are not shipped in the same external transport container as ~~the other organs~~, then the separate extra vessels external transport container must include the same complete donor documentation ~~as the organ~~.

16.5 Verification and Recording of Information before Shipping

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

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

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

1. Record each item placed into the external organ package

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

16.6 Extra Vessels Recovery, Transplant, and Storage

16.6.A Deceased Donor Extra Vessels Recovery and Transplant Use and Sharing

~~To recover and use vessels in an organ transplant, the deceased donor authorization forms must include language indicating that the vessels will be used for transplant. The Extra vessels can must only be used for organ transplantation or modification of an organ transplant. Transplant hospitals may share deceased donor extra vessels with other transplant hospitals. Extra vessels from a living donor must only be used for transplant or modification of an organ transplant for the original intended recipient and must not be shared. If sharing occurs between transplant hospitals, the receiving transplant hospital must submit a detailed explanation to the OPTN Contractor that justifies why the sharing occurred. The Membership and Professional Standards Committee (MPSC) will review the explanation. If the receiving transplant hospital later disposes of any vessels, it must notify the OPTN Contractor.~~

16.6.B Extra Vessels Storage

Transplant hospitals must not store a donor's extra vessels if the donor has tested positive for *any* of the following:

- HIV by antibody, antigen, or nucleic acid test (NAT)
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B (HBV) by NAT
- Hepatitis C (HCV) by antibody or NAT

Extra vessels from donors that do not test positive for HIV, HBV, or HCV as above may be stored. When a transplant hospital stores extra vessels it must do *all* of the following:

1. Use stored extra vessels *only* for organ transplantation
2. Designate at least one person to monitor extra vessels storage, use, destruction, and reporting
3. Package and label extra vessels as required by *Policy 16.3: Packaging and Labeling* and *Policy 16.4: Documentation Accompanying the Organ or Extra Vessels*
4. Store extra vessels in a Food and Drug Administration (FDA) approved preservation solution
5. Store extra vessels in a secured refrigerator with a temperature monitor and maintain the temperature no colder than 2 degrees Celsius and no warmer than 8 degrees Celsius
6. Maintain a log of stored extra vessels
7. Maintain all records relating to the monitoring and use of extra vessels
8. Monitor extra vessels daily and log security and refrigerator temperature checks
9. Destroy unused extra vessels within 14 days after the recovery date
10. ~~Report the extra vessel's use or destruction to the OPTN Contractor within seven days of the transplant hospital's use or destruction of the extra vessels~~

~~16.6.C — Blood Type Verification Prior to Transplant of Deceased Donor Vessels~~

~~The transplant hospital must verify the blood type, all infectious disease testing results, container contents, date of expiration, and the Donor ID of the vessels with the blood type and all infectious disease testing results of the recipient prior to transplant. These verifications must be documented and maintained in the recipient medical record.~~

~~16.6.DC — Recovery and Storage of Vessels from Living Donors — Reporting Requirements for Extra Vessels~~

~~A recovery hospital may only recover extra vessels for transplant if the living donor consents to the removal of extra vessels for transplant. The vessels from a living donor can only be used for transplant or modification of an organ transplant for the original intended recipient and may not share them with anybody else. Transplant hospitals must store vessels recovered according to *Policy 16.6.B: Vessel Storage*.~~

~~Transplant hospitals must report to the OPTN Contractor the disposition of all extra vessels, including their use, sharing, or destruction, within seven days of their use, sharing, or destruction.~~

~~16.6.E — Blood Type Verification Prior to Transplant of Living Donor Vessels~~

~~Prior to transplant, the recovery hospital must verify *all* of the following:~~

- ~~1. The living donor's blood type~~
- ~~2. The living donor's blood subtype, if used for allocation~~
- ~~3. All infectious disease testing results~~
- ~~4. Container contents~~
- ~~5. Date of expiration~~
- ~~6. Donor ID~~

~~The transplant hospital must also verify the blood type and subtype of the intended recipient, if used for allocation, and all infectious disease testing results of the recipient prior to transplant. The documentation of these verifications must be maintained in the recipient medical record.~~

[Subsequent headings and cross-references to headings affected by the re-numbering of this policy will also be changed as necessary.]

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