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Briefing Paper

Extra Vessels: Reducing Reporting Burdens and Clarifying Policies

OPTN/UNOS Operations and Safety Committee

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Contents

Executive Summary	1
What problem will this proposal address?	2
Why should you support this proposal?	3
How was this proposal developed?	4
How well does this proposal address the problem statement?	6
Was this proposal changed in response to public comment?	8
Which populations are impacted by this proposal?	11
How does this proposal impact the OPTN Strategic Plan?	11
How will the OPTN implement this proposal?	12
How will members implement this proposal?	12
Transplant Hospitals	12
OPOs	12
Will this proposal require members to submit additional data?	12
How will members be evaluated for compliance with this proposal?	12
How will the sponsoring Committee evaluate whether this proposal was successful post implementation?	13
Policy or Bylaws Language	17

Extra Vessels: Reducing Reporting Burdens and Clarifying Policies

Affected Policies:	*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: Organ and Vessel Packaging, Labeling, Shipping, and Storage, 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 16.6.E: Blood Type Verification Prior to Transplant of Living Donor Vessels*
Sponsoring Committee:	*Operations and Safety Committee*
Public Comment Period:	*January 22, 2018 – March 23, 2018*
Board of Director's Date:	*June 11-12, 2018*

Executive Summary

This proposal would change requirements when extra vessels are shared among transplant hospitals. Members would no longer need to submit a justification to the Membership and Professional Standards Committee. Instead, they will report sharing to the OPTN Contractor through the existing extra vessels reporting system in UNetsm. Proposed IT programming will allow OPOs to view extra vessel dispositions from donors that they recovered.

This proposal would also change extra vessels policy labeling requirements for infectious disease results by narrowing labeling from "all" to only "HIV, hepatitis B (HBV), and hepatitis C (HCV)" results. This will facilitate aligning test results and names among OPTN Contractor IT systems (e.g. DonorNet®, TransNetsm) and the label. A TransNet barcode will be added to the label to allow scanning and accessing all infectious disease results available in DonorNet.

This proposal will align policy language with the Final Rule indicating that vessels (including extra vessels) are considered part of the organ with which they are recovered and subject to applicable requirements. Some current policies need clarifications, exclusions, or deletions to fit within the federal regulation logic and framework.

What problem will this proposal address?

This project addresses three problem areas.

1. Change Extra Vessels Sharing Requirements
2. Change Extra Vessels Label Policy Requirements and Align DonorNet and Extra Vessels Label
3. Align OPTN Extra Vessels Policies with Final Rule

Part One: Change Extra Vessels Sharing Requirements

Current policy requires receiving transplant hospitals to submit a justification to the OPTN/UNOS Membership & Professional Standards Committee (MPSC) when extra vessels are shared among OPTN transplant programs. The existing requirement, first enacted in 2005, results in the MPSC reviewing over 50 justifications each year. During 2016-17, 115 justifications were reviewed. No member violations have ever resulted from these reviews. The review is not an efficient use of member, staff, or volunteer time. In August 2015, a comprehensive extra vessel tracking and reporting system was implemented in the OPTN Contractor's UNet^{sm} data collection system as part of the Transplant Information Electronic Data Interchange (TIEDI®). This system provides information needed for monitoring of shared extra vessels. Current policy is outdated, no longer needed, and should be amended. Changing the requirement will reduce both unnecessary burden while maintaining safety through another existing system already being used.

Part Two: Change Extra Vessels Label Policy Requirements and Align DonorNet and Extra Vessels Label

The transplant community has questioned differences between various extra vessel infectious disease reporting mechanisms and requested that they be changed. Current policy requires that all infectious disease testing results be printed on the extra vessels label that is attached to the outermost layer of the triple sterile barrier. With additional testing being completed for emerging or endemic agents (e.g. West Nile Virus, Zika, Chagas), managing the ability to report all infectious disease results on the extra vessels labels becomes complex. Members do not record these extra tests on the infectious diseases tab in DonorNet. Users can type up to three "other" test results in TransNet but at times this is not enough as more than three additional tests are being performed. Currently DonorNet and the extra vessels label are not consistent in either the names of the infectious disease tests nor the test result choices. TransNet, which is now mandatory for OPO use for all labeling and packaging, prints the DonorNet tests that are currently on the extra vessels label. Differences between test names and result options creates confusion. The policy, as well as all tools used to communicate infectious disease results, must be re-examined and updated for clarity and consistency to meet identified concerns.

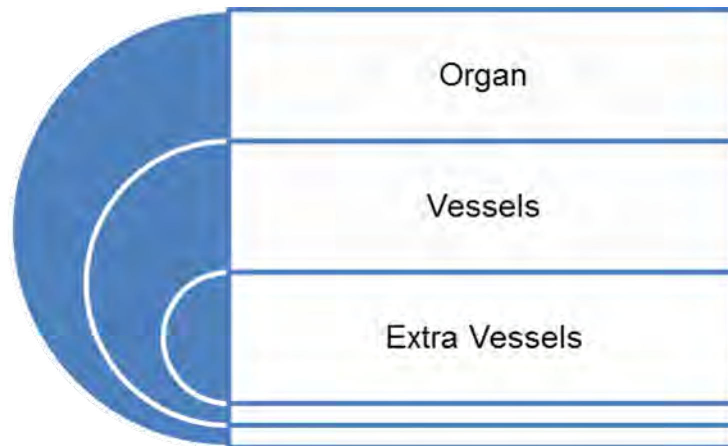
Part Three: Align OPTN Extra Vessels Policies with Final Rule

The Final Rule states that OPTN organ policies also apply to vessels. Section §121.2 of the Final Rule contains the following definition for an organ: "*Organ means a human kidney, liver, heart, lung, pancreas, intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract) or vascularized composite allograft (defined in this section). Blood 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 if the vessels are intended for use in organ transplantation and labeled "For use in organ transplantation only."*" In addition, §121.7, part (e) (Identification of organ recipient) states "*A blood vessel that is considered part of an organ under this part 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.*"[1] These clarifications were added when authority to oversee extra vessels used in transplantation were transferred from the Food and Drug Administration (FDA) to Health Resources and Services Administration (HRSA) following a 2006[2]

[1] OPTN Final Rule https://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5.
[2] Proposed Rule: https://www.federalregister.gov/documents/2006/05/12/06-4370/blood-vessels-recovered-with-organs-and-intended-for-use-in-organ-transplantation-companion-document

proposal that was finalized in 2007.[3] Using the Final Rule definitions, all “extra vessels” are types of “vessels” and all “vessels” are considered part of “organs” (Figure 1).

Figure 1: Relationship of Organs, Vessels, and Extra Vessels



Policies inconsistently treat vessels as though they are part of the organ with which it was procured. For example, there are organ-specific policies such as documentation of abnormalities that do not need to apply to extra vessels. Various policies have organ requirements and therefore include extra vessels. The citation to extra vessels is not necessary. Examples of these policies incorporate this logic already include extra vessels and do not need to specifically call out extra vessels. Some of these policies include some of the packaging and labeling requirements as well as infectious disease reporting. In other cases, specific exclusions or alterations need to be proposed. An example of this type of proposed change includes allowed emergency use of organs when HIV screening has not been completed. While the extra vessels could be used in the original transplant, they could not be stored without the HIV results. Current policy is silent on this but the proposal will provide clarification.

Why should you support this proposal?

Part One: Change Extra Vessels Sharing Requirements

The proposed policy solution will change the reporting requirement for extra vessels sharing. The member receiving the extra vessels will no longer submit a justification to the MPSC when extra vessels are shared. The member sending the extra vessels will be required to report the sharing in the existing TIEDI system within seven days of the sharing. This solution reduces member, staff, and MPSC volunteer burden for a requirement that has not found any policy violations. The functionality for transplant hospitals to report sharing currently exists in the TIEDI system.

Part Two: Change Extra Vessels Label Policy Requirements and Align DonorNet and Extra Vessels Label

The proposed policy solution will also clarify the current policy requirement that "all infectious disease results" must be on the extra vessels label. It will standardize both tests and results that will be required to be on the label yet provide a more flexible and adaptable solution for accessing other infectious disease test results. This will provide the most up to date results as well as better highlight extra vessels that cannot be stored if not used with the organ with which they were sent. This will facilitate better safety practices and help reduce violations.

Part Three: Align OPTN Extra Vessels Policies with Final Rule

The third part of the proposal will clarify other OPTN policies to ensure consistency with the Final Rule. The clarifications will reduce existing policy ambiguities raised by staff analysis as well as member questions. Extra vessels questions have resulted in numerous policy interpretation questions.

[3] Final Rule: https://www.federalregister.gov/documents/2007/03/12/07-1131/blood-vessels-recovered-with-organs-and-intended-for-use-in-organ-transplantation

How was this proposal developed?

This proposal was developed in collaboration with multiple internal and external stakeholders.

Part One: Change Extra Vessels Sharing Requirements

The MPSC in consultation with UNOS staff requested that the justification required for extra vessels sharing be reconsidered. In the past two years (2016-2017), 115 justifications have been submitted and reviewed for an average of 58 per year. The justification reviews have not found any safety concerns or policy violations. The Operations and Safety Committee agreed that this requirement was no longer needed. They discussed the need to continue to have a tracking mechanism when extra vessels are shared to facilitate timely communications for safety concerns such as infectious diseases. They propose having shared vessels reported through the existing TIEDI system. The requirement would be for the sending hospital to report within seven days as is the existing policy time frame to report use or destruction. The receiving hospital can currently report extra vessels dispositions regardless of whether the sending hospital has reported the dispositions. Members are currently using this function although it is optional and not currently policy-required for sharing.

Part Two: Change Extra Vessels Label Policy Requirements and Align DonorNet and Extra Vessels Label

The TransNet Work Group of the Operations and Safety Committee developed recommendations for the proposed policy changes to the extra vessels label that is placed on the outermost layer of the triple sterile barrier. The TransNet Work Group includes representatives from the Organ Procurement Organization, Transplant Administrators, and Transplant Coordinators Committees as well as end users from both OPOs and transplant hospitals. This group reviewed data and considered three options to rectify the issues identified. Currently, the infectious diseases screening page in DonorNet does not record tests that some OPOs perform due to regional concerns (e.g. Strongyloides). The current policy requires that all infectious disease results be on the label and some OPOs have had difficulty because there are only three “other” spots on the current label. The work group identified these issues and considered three options:

1. Keep policy as is and make the polyplastic labels bigger. Print four versus three TransNet labels.
2. Limit label results to policy-required tests (have bar code scan for additional results)
3. Limit label results to HIV, HBV, and HCV test results (have bar code scan for additional results)

The TransNet Work Group recommended option three. The Ad Hoc Disease Transmission Advisory Committee (DTAC) also recommended option three as well. DTAC members stated that other results (e.g. CMV) are not likely to stop use of extra vessels in an emergency although follow up would need to be done afterwards. The Operations and Safety Committee discussed the recommendations and agreed that the proposal would limit extra vessels label results to HIV, HBV, and HCV test results and then a bar code would be added through TransNet labeling to facilitate a scan for all other results. The results will be the most up-to-date results available in DonorNet.

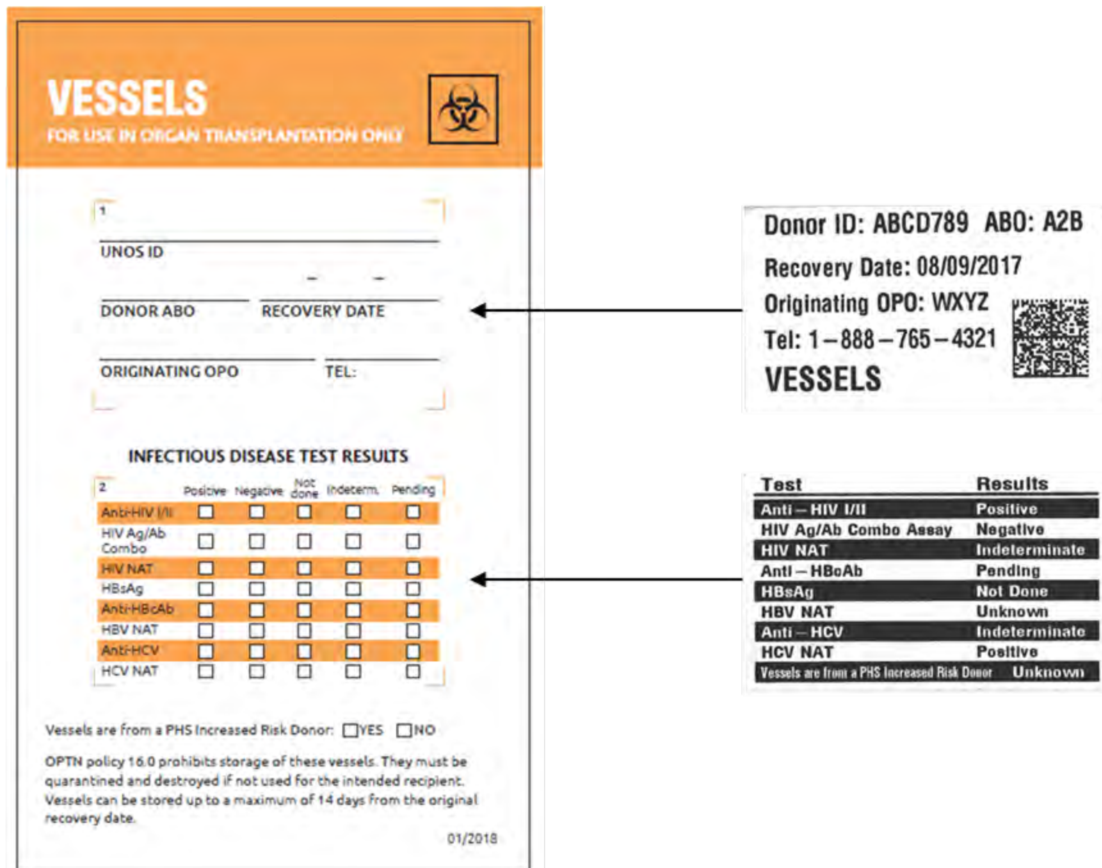
Reasons in support of this recommendation include that the polyplastic label and TransNet programming could be maintained without the need for frequent changes. Having the barcode scan for the most recent results could help promote use of TransNet among transplant hospitals. There will be the ability to better identify those vessels which cannot be stored. It will be possible to add additional tests in DonorNet if desired without making as many changes downstream that take significant time and resources to implement. The results that are most likely to be pending at recovery will then get a scan for the most recent results. Currently, there is no requirement to update the results on the extra vessels label or from the TransNet label data.

Another change that the Committee is proposing is to eliminate the “unknown” test result option in UNet and then to modify the extra vessels label accordingly to align five test result options between DonorNet and the extra vessels label. These test result options will be positive, negative, indeterminate, pending, and not done. Currently the extra vessels label only has four options and one of them is “N/A” which is not a DonorNet option. The choices “indeterminate” and “not done” are currently not on the label but will be added. See Table 1 and Figure 1 below.

Table 1: Comparison of Current and Proposed Test Result Options in DonorNet and Extra Vessels Label

Test Result Options	Positive	Negative	Pending	Not Done	Indeterminate	Unknown	N/A
Current							
Donor Net	X	X	X	X	X	X	
Extra Vessels Label	X	X	X				X
Proposed							
Donor Net	X	X	X	X	X		
Extra Vessels Label	X	X	X	X	X		

Figure 2: Proposed DRAFT Extra Vessels Polyplastic and TransNet Labels



The Committee recognizes the need to access other test results such as CMV, EBV, as well as other discretionary testing done based on local protocols. The TransNet label that is affixed to the extra vessels label will have a bar code scan that can access all infectious disease results in DonorNet. The Committee requests specific public comment feedback on what other tests are routinely done (e.g. Strongyloides) so that these can be considered for addition in DonorNet.

Part Three: Align OPTN Extra Vessels Policies with Final Rule

UNOS staff analyzed OPTN/UNOS policies that mention extra vessels as well as organ policies that could apply to extra vessels in light of the logic in the Final Rule. This analysis was conducted following extra vessels policy interpretation questions. The Final Rule, as modified in 2007, states that vessels (including

extra vessels) are subject to allocation requirements and policies for the organ for which they were procured. Not all policies were written using this logic as many policies were developed before it was written. OPTN/UNOS policies and Final Rule terms differ slightly. When the term "vessels" is used in the Final Rule it means both vessels attached to the organ as well as what the OPTN defines as "extra vessels." In addition, policies sometimes uses the term "vessels" versus "extra vessels" although the intent is governing extra vessels.

Staff considered three options to remedy the inconsistencies.

1. Create a separate extra vessels policy
2. Develop exclusionary policy where needed (e.g. Vascularized Composite Allografts or VCAs)
3. Keep status quo, but clarify as needed

Staff originally thought a separate policy might be more user friendly, but after testing this model, realized that developing an exclusionary policy made the most sense. In addition, all references to "vessels" were clarified to reflect the true intent of "extra vessels".

In the proposed changes, the terms "vessels" or "extra vessels" are removed when they should not be in policy since extra vessels are considered part of the organ with which they were recovered. It is very important to note that the policy requirements still apply to extra vessels. It will be important for the transplant community to include extra vessels, unless specifically excluded, when complying with organ policies.

Staff identified several areas where Committee consultation was needed. These areas were discussed by the Committee, and the following decisions were made:

1. No extra vessels exceptions were needed for:
    - Documenting surgical damage or abnormalities
    - Tissue typing specimen requirements
    - Transportation costs
2. Clarifications were added to several policies. These include:
    - Allowing use of extra vessels in HIV exceptions only for the primary non-kidney transplant
    - Extra vessels must only be recovered as part of an organ recovery and not in isolation
    - Extra vessels must be sent as part of an organ following recovery. Although they can be packaged separately, they must accompany an organ.
    - Release of organs policies apply when the organ that is released back to the OPO included extra vessels as part of the organ. However, once it is determined that the extra vessels are not needed for the original primary intended recipient, they can be shared between transplant hospitals (not released back to the OPO)
    - Existing verification policies were combined and clarified to apply to transplant in secondary recipients or organ modification procedures. The infectious disease verification requirement was changed from "all" to "HIV, HBV, and HCV" results for consistency with other proposed changes and because those are the results affecting whether extra vessels use is prohibited.
    - When PHS increased risk extra vessels are used in an emergent situation and informed consent could not be obtained before the procedure, then the recipient can be informed after their use and followed with the program's post-transplant increased risk testing protocol

Further details on the proposed changes are documented and summarized in Appendix A.

How well does this proposal address the problem statement?

Part One: Change Extra Vessels Sharing Requirements

The MPSC now reviews over 50 extra vessels justifications per year. During 2016-2017, they reviewed 115 justifications with no resulting policy violations.

Data show that between January 1, 2016 and June 30, 2017, 14,381 extra vessels dispositions were reported through the TIEDI reporting system implemented in August 2015. During that same period, 99% of donors with at least one organ reported as sent with extra vessels in DonorNet. Of the dispositions reported, there were 103 reports of extra vessels being sent to another hospital. This demonstrates high acceptance and use of the reporting system. The proposed change from requiring a justification to requiring reporting within TIEDI allows for timely tracking. To some extent, it is already being done by the transplant community.

Between January 1, 2017 and June 30, 2017, there were 4,775 dispositions reported and 444 (9.3%) were outside of the seven-day reporting requirement. The proposed requirement to report within seven days is the same timeframe for reporting use or destruction. The data suggest that awareness efforts may be needed for timelier reporting. The majority of extra vessels (98.3%) are reported as transplanted or destroyed within the 14-day period from recovery date and there was only one case where the extra vessels disposition was reported outside of the possible maximum window (21 days after recovery).

Part Two: Change Extra Vessels Label Policy Requirements and Align DonorNet and Extra Vessels Label

The decision to align test result options was made based on community requests and TransNet work group feedback. The decision to remove “unknown” as an DonorNet option was made based on confusion over the term’s definition and very low current use (used for only 10 donors in 2016) that indicates that this change should not have major impacts.

The decision to limit the extra vessels label to HIV, HBV, and HCV results is based on printing results that are available at the time of label generation and limiting results to those that affect storage requirements.

Of the 4,775 extra vessels reported between January 1, 2017 and June 30, 2017, 299 tested positive for HCV (antibody or NAT), HBV (surface antigen or NAT), or HIV (antibody, combo antigen/antibody, or NAT) as stated by policy. While 96.3% of these extra vessels were transplanted or properly disposed (288), 3.7% (n=11) were stored in violation of policy4.

Data analyzed at time of TransNet infectious disease result validation show that only 1.1% or less of HIV, HBV, and HCV results are pending compared to over 11% for EBV results and up to 15% for “Other” results. The data indicate that 5.4% of extra vessels are NAT positive indicating likely active viremia as well as a storage prohibition if not used in the intended recipient. Table 2 below shows extra vessels label results.

Table 2: TransNet Infectious Disease Validations from June 1, 2017 to October 24, 2017

Infectious Disease	Indeter minate	Negative	Not Done	Pending	POSITIVE	Unk.	No Data	Total	% Pending*	% Positive*
Anti-CMV	12	1716	1	38	2731		756	5254	0.8	60.7
Anti-HCV		4103		39	360		752	5254	0.9	8.0
EBV-IgG	19	251	198	479	3546		761	5254	11.2	82.6
EBV-IgM	14	3103	931	402	41	1	762	5254	11.3	1.2
HBcAb		4261	3	42	195	1	752	5254	0.9	4.3
HBsAg		4452	2	34	6		760	5254	0.8	0.1
HIV I/II		4411	42	38	10		753	5254	0.9	0.2
NAT HBV	1	4433	2	51	14	1	752	5254	1.1	0.3
NAT HCV	1	4203	2	51	244	1	752	5254	1.1	5.4
NAT HIV	1	4443	3	51	3	1	752	5254	1.1	0.1
Other 1	16	3165	1	277	434		1361	5254	7.1	11.2

[4] United Network for Organ Sharing Research Department. Extra Vessel Disposition Reporting Database Evaluation. OPTN/UNOS Descriptive Data Analyses. Prepared for the Operations and Safety Committee. October 25, 2017.

Infectious Disease	Indeterminate	Negative	Not Done	Pending	POSITIVE	Unk.	No Data	Total	% Pending*	% Positive*
Other 2	15	1803	11	267	232		2926	5254	11.5	10.0
Other 3	11	708	7	145	100	1	4282	5254	15.0	10.4
RPR/VDRL		4346	69	33	44	2	760	5254	0.7	1.0
Totals	90	45398	1272	1947	7960	8	16881	73556		

*(if data entered to indicate test was done)

Data obtained from the OPTN database on October 24, 2017.Data subject to change based on future data submission or correction.

Part Three: Align OPTN Extra Vessels Policies with Final Rule

The staff analysis included all policies that affect organs or extra vessels. Half of the references identified and evaluated needed some change or further action. See Table 3 below.

Table 3: Staff Analysis of OPTN Policy

Change Current Policy Reference?	Count
No	49
Yes	39
Committee consultation needed	6
Move	5
Total	99

In addition, there have been over 25 member or staff questions in the past several years resulting in formal analysis for policy interpretation. These data support making changes that are required by the Final Rule and will assist with member implementation.

Was this proposal changed in response to public comment?

Yes, there were changes made to the proposal in response to public comment.

During the public comment period (January 23 – March 23, 2018), this policy proposal received 18 comments on the OPTN website. Comments included input and feedback from OPTN/UNOS Committees, professional societies, and regions. The Operations and Safety Committee held two webinars for other OPTN/UNOS Committees that were interested in the proposal. The proposal was also presented during a national webinar open to the public. Three committees provided feedback on the OPTN website (Membership and Professional Standards Committee (MPSC), Ad Hoc Disease Transmission Advisory Committee (DTAC), and Organ Procurement Organization (OPO) Committee). The DTAC provided recommendations to the Committee during the development of the proposal. They support the proposal as written as does the OPO Committee. The MPSC supported the proposal but did voice concerns regarding the difficulties in training OR staff in new technologies. In addition, five professional societies provided support for this proposal moving forward to the OPTN/UNOS Board of Directors. These include the American Society for Histocompatibility and Immunogenetics (ASHI), Association of Organ Procurement Organizations (AOPO), North American Transplant Coordinators Organization (NATCO), American Society of Transplant Surgeons (ASTS), and American Society of Transplantation (AST). All eleven regions discussed the proposal. Every region unanimously approved the proposal.

The Operations and Safety Committee asked for specific feedback on what additional infectious disease testing is conducted due to donor travel history or other local protocols but not mandated by national policy so that these tests can be considered as possible optional additions in DonorNet. DTAC, AST, and

Region 2 provided feedback that highlighted testing for Strongyloides at a number of OPOs. Given that many OPOs perform testing for this infectious disease, Committee members agreed that changes in DonorNet were valuable for ease-of-use and applicability. As such, Strongyloides will be added to the DonorNet Infectious Disease Screening tab. While it is not a policy requirement to perform donor Strongyloides testing, the addition will make entering and finding results for this test easily accessible.

Several other themes emerged from public comment:

3. The implementation of the extra vessels barcode and associated technological and training barriers that affect transplant hospitals
4. Improving communications on extra vessels
5. Revisiting policies and potential new policies

Implementation of the extra vessels barcode

The MPSC supported the proposal but raised concerns over the implementation of the extra vessels storage barcode. In particular, the MPSC expects significant technology and training barriers in the use of this barcode. Feedback provided by Region 11 stated that operating room staff may struggle using the barcode, especially since many operating room staff may not be familiar with transplant medicine and procedures. Furthermore, the MPSC stated that difficulties may arise during implementation in transplant hospitals. These difficulties include limited availability of compatible barcode scanners; lack of ability to relabel with TransNet; lack of routine practice due to infrequent extra vessels use after storage or sharing; and requiring major process changes at transplant hospitals.

Upon reviewing this feedback, Committee members noted that no new requirements were being placed on transplant hospitals for the use of TransNet. The barcode is being added simply as an enhancement, not a requirement. In addition, this policy proposal will change prior OPTN Policy stating that all infectious diseases must be verified before transplanting extra vessels into a recipient. As a result of these changes, only HIV, HBV, HCV will be required, decreasing the verification burden. Finally, there are three options for viewing test results: paper, DonorNet, or scanning the barcode. Transplant hospitals will be able to choose their preferred method of viewing results to complete the basic requirements for examining HIV, HBV, and HCV results to determine storage ability or verification. The barcode scan is an enhancement that will assist with accessing real-time up to date results for all infectious diseases that are entered in DonorNet.

The Committee, however, is aware of the realities that operating room staff face in a fast-paced, high-pressure environment. The Committee also recognizes that operating room hospital staff must adhere to many protocols and procedures and that they may not be familiar with transplant specific processes. Additional functionality available with the barcode scan could create short-term difficulties during implementation. Nevertheless, Committee members believe that adding barcodes as an enhancement to extra vessels storage and usage will both increase patient safety as well as provide transplant hospitals with cutting-edge options for efficiency. The Committee is committed to working with member organizations to provide proper outreach and educational communications for the process of implementation if transplant hospitals opt to utilize extra vessels barcodes. The use of TransNet and accessing infectious disease results available through DonorNet is voluntary not required.

Improving communications on extra vessels

There were several suggestions directed at improving communications by OPTN/UNOS Committee members, professional societies, and regions. These suggestions include the following:

- Adding policy language requiring transplant hospitals to notify OPOs if extra vessels are used in a secondary recipient to ensure communication of additional donor information and potential disease transmissions (OPO Committee)
- Including information regarding extra vessels in Potential Donor Derived Disease Transmission Event (PDDTE) notifications (AST)
- Including both the UNOS ID and the corresponding match ID on TransNet labels, given that scanning capabilities are not always available (Region 6)

- Notifying OPOs when extra vessels are shared via a TransNet alert (Region 7)
- Managing new information post-transplant for stored donor vessels (Region 8)

Committee members carefully considered all these communication suggestions. OPOs will be given access to the OPTN extra vessels reporting system within TIEDI. This will facilitate communication and the ability of the OPO to know the disposition of extra vessels that they have recovered. The information can be shared or entered on the PDDTE as available. The issue with transplant hospital's needing a match ID to access information in DonorNet is known and solutions are being considered within the broader UNOS IT departments. The bar code will be the first step in providing more up to date information regarding the donor testing status. It might be possible in the future to add additional information (e.g. other test results such as cultures).

The Committee discussed the Region 1 concern and suggestion. Current OPTN data is silent on this pathway although nearly all (99%) of extra vessels dispositions are reported to the OPTN since the new reporting system in TIEDI was implemented in 2015. Committee members agreed that a data request is warranted to gain insight into the occurrence of transplant hospitals requesting that an OPO provide extra vessels for a planned living donor procedure. An OPTN data request will be developed. After reviewing available data and patterns of this occurrence, the Committee will formulate next steps.

Revisiting policies and potential new policies

Other public commenters mentioned areas where current policies should be revised or new policies should be considered.

- Since OPTN policy prohibits programs from storing vessels positive for HBV, HCV, and HIV, look at requirements to verify all infectious disease testing results of the extra vessels and all infectious disease testing results of the recipient prior to transplant (Region 7)
- Why ban storing of HCV positive extra vessels-Use of HCV positive organs growing and treatment available (Region 8)
- Considering pathways for documenting events when transplant hospitals request extra vessels from OPOs for living donor procedures (Region 1)
- Modify the label to reflect that recovery date means when the donor entered the OR (Region 2)

Comments were provided which questioned the ban on storing HCV-positive extra vessels, specifically given the increase in available treatments (Region 8). The Committee appreciates and is aware of the increased usage of positive HCV extra vessels, but at this time, no changes were made to OPTN Policy. As such, HIV, HBV, and HCV are not allowed to be stored with the exception of HBV-core positive extra vessels. Since OPTN Policy prohibits transplant hospitals from storing extra vessels positive for the aforementioned infectious diseases, Region 7 requested insight into requirements to verify all infectious disease testing results of the extra vessels and all infectious disease testing results of the recipient prior to transplant. In an effort to further clarify policy, the Committee removed recipient infectious disease results verification as it gives the false impression that donor positive extra vessels can be stored and transplanted within positive recipients. It also did not make sense to keep this since the verification requirements will be limited to the HIV, HBV, or HCV versus "all". Further clarifications includes changing policy label infectious disease names to match label names (Anti-HBcAb to anti-HBc).

Region 2 voiced concern on the subject of recovery date. Currently, there is no definition for recovery date in OPTN Policy. The only definition is in help documentation in DonorNet that states that the recovery date is the day that the donor entered the operating room. This can get confusing as the cross-clamp date can vary if recovery goes past midnight. In fact data suggest that there are approximately 7 percent of cases where recovery date and cross clamp date do not match. This has a downstream impact on when the extra vessels expire. OPTN policy requires that extra vessels be used or destroyed within 14 days of the recovery date. Policy violations may be incurred since cross clamp time can potentially be a different date than entry into the operating room. The other confounding factor is that TransNet is a point of care labeling system. Labels are printed in real time as is the best practice to avoid labeling mix ups. The current date automatically populates into the extra vessels label and must be manually changed if the current recovery date was a day earlier (before midnight).

Region 2 had suggested modifying the label to read “time donor entered OR” rather than “recovery date” to avoid this confusion. Committee members agreed that the lack of clarity regarding recovery date warrants policy changes. However, the substantive changes necessary to clarify recovery date and the potential impacts on existing data will require a new round of public comment. In the new public comment proposal, recovery date will potentially be defined as cross clamp date. This proposed change to define recovery date as cross clamp date can work within the current system. Furthermore, OSC consulted with the OPO Committee and the Data Advisory Committee (DAC) leadership. They support pursuing policy changes on defining recovery date as cross clamp date. The Operations and Safety Committee will continue to pursue this potential policy change for the next round of public comment.

The Operations and Safety Committee met for their in-person meeting on April 11, 2018 in Richmond, Virginia. They agreed to the following proposal language changes post public comment:

- Addition of prohibition of sharing to extra vessels that have not yet had completed HIV testing for the emergency use of organs not yet tested. Once testing is complete then regular policies apply.
- Further consolidation of extra vessels verification requirements. Movement of verification sections currently in Policy 16 to verification sections in Policy 5 for ease of use. Removal of requirement to verify recipient infectious disease results.
- Made all label names consistent with DonorNet. Change DonorNet and extra vessels label requirements for hepatitis B core antigen testing to anti-HBc for proper nomenclature and to be consistent with CDC terminology.
- Changed “may” to “must” to further clarify that living donor extra vessels are allowed for use only in the living donor recipient
- Other minor edits for style, consistency, and clarity

They voted unanimously (17 in favor-0 opposed) to send the policy proposal to the OPTN/UNOS Board of Directors for consideration at their June 2018 meeting.

Which populations are impacted by this proposal?

OPO and transplant hospitals who recover and use extra vessels. All 58 OPOs recover extra vessels. The majority, 156 out of 252 (62%) active transplant hospitals, had at least one extra vessels disposition reported to the OPTN Contractor in 2016.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no expected impact to this goal.
2. *Improve equity in access to transplants:* There is no expected impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no expected impact to this goal.
4. *Promote living donor and transplant recipient safety:* The majority of the hours projected by IT will address issue #2 (Change Extra Vessels Label Policy Requirements and Align DonorNet and Extra Vessels Label). This affects both safety and efficiency. Having a scan available through TransNet for all of the most up-to-date infectious disease results for extra vessels will promote transplant recipient safety.
5. *Promote the efficient management of the OPTN:* Reducing unnecessary requirements such as the extra vessels justification will reduce member, staff, and volunteer burden. Clarifying other areas of policy (e.g. infectious disease results on labels) will promote the ability to comply with requirements. Addressing all three issues will improve efficiency.

How will the OPTN implement this proposal?

With changes to so many aspects of policy and the procedures they influence, it is likely that an educational effort will be necessary. Professional Education will monitor this proposal as it develops.

This proposal will require the following programming in UNet℠:

1. Retire "unknown" as an option for DonorNet Infectious Disease screening page results. This will cascade to the Deceased Donor Registration (DDR) form and vice versa. No data conversion will be performed for historical records. This is needed to align DonorNet results with proposed revised extra vessels label.
2. Provide test additions to existing list on the Infectious Diseases page in DonorNet pending feedback from public comment.
3. Modify TransNet to new extra vessels label requirements that will only include HIV, HBV, and HCV results on the printed label but will include a bar-code label that calls back to DonorNet to display all infectious disease results.
4. OPO access to view extra vessels dispositions recorded in TIEDI for extra vessels recovered by the OPO. This is needed for OPOs to comply with infectious disease reporting.

This proposal will also require that the polyplastic extra vessels label be modified. Based on the outcome of the proposal, a draft label will be designed by staff for review by the Operations and Safety and Organ Procurement Organization Committees. Once approved, a new label will be ordered and posted as available for purchase on the UNOS store. Members will be provided guidance on when the new label must go into use through the traditional policy notice and OPTN news release.

How will members implement this proposal?

Transplant Hospitals

Transplant hospitals will have a reduced impact in that they would not have 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 in TIEDI within seven days of sharing. Transplant hospitals that receive extra vessels will continue to report their use or destruction to the OPTN Contractor in TIEDI within seven days of their use or destruction.

OPOs

OPOs will have to train staff on changed rules and possible changed data entry in DonorNet. If additional testing results are incorporated into DonorNet, then data vendors will need to be informed to change data mining and exporting practices. OPOs will have to purchase and use the revised extra vessels labels.

Will this proposal require members to submit additional data?

This proposal will require that transplant hospitals report sharing of extra vessels within seven days of the sharing. This proposal takes away the burden to submit a justification for sharing so the net effect will be less data submission. This is based on the data principle collection to maintain patient safety where no alternative data source exists.

How will members be evaluated for compliance with this proposal?

The proposed language will not require additional routine monitoring of OPTN members. Any data submitted to the OPTN Contractor may be subject to OPTN review, and members are required to provide documentation as requested. The MPSC will stop reviewing justifications for sharing since they will no longer be required.

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

This policy will be formally evaluated approximately six months and one year post-implementation. If needed, additional analyses after one year will be performed at the request of the Committee. The OPTN will monitor the following data to assess the impact of policy change:

1. Trends in the number of extra vessels reported as shared in the TIEDI® Extra Vessels Disposition Reporting Database post-policy change vs extra vessels reported to MPSC pre-policy.
2. Trends in the number of patient safety events related to testing and labeling pre vs post policy change.
3. Trends in the number of HCV, HBV, and HIV positive extra vessels stored in violation, pre vs post policy change.

The policy change, if successful, should not result in significant changes and could capture additional sharing events.

APPENDIX A: 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.
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 into Policy 16.6.C

Policy or Bylaws Language

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

RESOLVED, that changes to *Policies 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:Organ and Vessel Packaging, Labeling, Shipping, and Storage, 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 *16.6.E: Blood Type Verification Prior to Transplant of Living Donor Vessels* as set forth below, are hereby approved, effective September 1, 2018, except the following changes in *Policy 16.3.D: Internal Labeling of Vessels Packaged Separately from Other Organs, lines 367-376*, which will go into effect pending implementation and notice to OPTN members.

1.2 Definitions

Extra vessels

~~A v~~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
6. 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
7. 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 a~~n 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	• 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.*
7. (~~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 originall~~y~~ ~~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:

1. Inform the recipient of the use of the extra vessels and the increased risk status
2. 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 ~~V~~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 extra vessels ~~is~~ are for use in organ transplantation only	●	●
7. ~~All i~~Infectious disease donor screening test results for *all* of the following: **a. anti-HIV I/II** **b. HIV Ag/Ab combo** **c. HIV NAT** **d. anti-HBc** **e. HBsAg** **f. HBV NAT** **g. anti-HCV** **h. HCV NAT**		●

This information must be included:	On the rigid container:	On the outermost layer of the triple sterile barrier:
8. Whether the extra vessels are from a donor with a positive result (~~including~~ NAT included) for *any* of the following: • **~~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 extra vessels are from a donor that meets the 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*	●	●

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.~~D~~C ~~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:~~

469 ~~1. The living donor's blood type~~

470 ~~2. The living donor's blood subtype, if used for allocation~~

471 ~~3. All infectious disease testing results~~

472 ~~4. Container contents~~

473 ~~5. Date of expiration~~

474 ~~6. Donor ID~~

475
476 ~~The transplant hospital must also verify the blood type and subtype of the intended recipient, if~~
477 ~~used for allocation, and all infectious disease testing results of the recipient prior to transplant.~~
478 ~~The documentation of these verifications must be maintained in the recipient medical record.~~
479
480 *[Subsequent headings and cross-references to headings affected by the re-numbering of this*
481 *policy will also be changed as necessary.]*
482 #