Extra Vessel Recovery, Storage, and Transplant Policies

You will find this factsheet useful if you work for an organ procurement organization (OPO) or transplant center and have responsibilities related to the recovery, storage or transplant of extra vessels, or are responsible for following up with the OPTN on the disposal of these vessels. Information related to the final disposition of extra vessels is important to the transplant community and allows us to track the spread of potential infection or disease that may be transmitted from a donor. Transplant recipients sometimes receive extra vessels during organ transplant or for vascular reconstruction. As soon as any clinical information that would impact the care and follow up of these extra vessel recipients becomes available, we need to immediately communicate it to the transplant centers. However, if extra vessel disposition has not been reported, it can hamper timely and effective communication.

An extra vessel is defined by the OPTN as:
A vessel taken during procurement of deceased or living donor organ(s) with the intent to be used 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 (i.e. iliac artery or vein, aorta, carotid artery or jugular vein, etc.).

OPTN Policy 5.10 Vessel Recovery, Storage and Transplant

The intent of this policy is to permit:

- Vessel recovery and immediate use in a solid organ transplant (for example either a current liver or pancreas transplant); and
- Vessel recovery and storage for use in a subsequent solid organ transplant from a donor with a different UNOS Donor ID (for example, when the vessel(s) and the liver or pancreas allograft are being transplanted from different donors with different numbers).

5.10.1 Vessel recovery and transplant

- The consent forms used by the recovering OPO must include language that indicates that vessels will be used for transplant.
- The vessels cannot be used other than for the implantation or modification of a solid organ transplant.
- Vessels can be shared among transplant centers. If sharing occurs between transplant centers, the implanting program must submit to the OPTN a detailed explanation justifying the sharing. The justification will be reviewed by the Membership and Professional Standards Committee (MPSC). The implanting transplant program must notify the OPTN of subsequent disposition of the vessel(s).
- If the transplant center stores vessels and subsequently uses the vessels for the intended recipient or another transplant recipient, the OPTN must be notified.
- The transplant center must verify the ABO, all serology results, container contents, date of expiration, and the UNOS Donor ID of the vessel with the ABO and all serology results of the recipient prior to implantation. The documentation of this verification must be maintained within the recipient medical record and made available to the OPTN contractor upon request.
5.10.2 Vessel storage
The Transplant Center must designate a person to monitor and maintain records, destroy, and notify the OPTN of outcome and/or use of vessels. This designated person must maintain information on all donor vessels including monitoring and maintaining all records relating to the use and management of donor vessels (e.g. subsequent positive serology testing, monitor inventory of stored vascular conduits). This person must monitor the refrigerator, ensure records are up to date and available with the conduits, destroy the vessels when expired, and notify the OPTN of its use or disposal.

- Hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels may not be stored for subsequent use.
- The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).
- The vessels must be stored in a rigid, sterile sealed container and must be protected by a triple sterile barrier, one of which must be the rigid container labeled with the recovery date, ABO, ABO subtype when used for allocation, infectious disease results container contents, and the UNOS Donor ID for tracking. The standardized vessel label distributed by the OPTN contractor must be affixed to the outer most sterile barrier bag and information on the label must include recovery date, ABO, all infectious disease results, container contents, and the UNOS Donor ID. If the donor is in a “high risk” group as defined by the US Public Health Service (PHS) guidance, the label must indicate that the vessels are from a donor who meets the (PHS) criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state for use in organ transplantation only. If removed from the triple sterile barrier, the transplant center must re-label the vessels prior to storage.
- The vessel(s) must be stored in a secured refrigerator with a temperature monitor and maintained within a range of 2 - 8 degrees Celsius.
- There must be daily monitoring of the vessel(s) with documented security and temperature checks by the transplant center.
- The vessel(s) can be stored up to a maximum of 14 days from the original recovery date.
- The transplant center must maintain a log of stored vessels.
- The transplant surgeon must have around the clock access to the donor information prior to using the donor vessel(s) in a recipient other than the intended recipient.

How UNOS Site Surveyors Determine Compliance with Policy 5.10
Site surveyors will ask to review the center’s extra vessel storage policy/procedure and extra vessel storage log. This review will help the surveyors determine whether the center logged daily storage temperatures and documented the extra vessel disposition. Site surveyors will also interview the center’s staff responsible for monitoring and maintaining extra vessel records, destroying extra vessels, and notifying the OPTN of the final outcome of the extra vessels.

To ensure your center is in compliance with Policy 5.10 our surveyors will:

- Review documentation indicating that the OPTN was notified when extra vessels were used for either the intended recipient or a different transplant recipient
- Review documentation of extra vessels that were implanted to ensure that they were used only for the implantation or to modify a solid organ transplant
• Review the center’s process to ensure that the transplanting surgeons have 24/7 access to the extra vessel donor information before using that vessel in a recipient different from the recipient the extra vessel was originally intended for.

• Review any vessels currently stored to verify compliance with policy regarding:
   Refrigerator temperature and security
   Extra vessels labeled with the required OPTN label
   Extra vessels stored in a triple sterile barrier.

Important Facts to Remember
• Extra vessels are most commonly used in liver and pancreas transplants, but are occasionally used in intestine, kidney, multi-visceral, and thoracic organ transplants. Extra vessels are almost always used for a pancreas transplant.

• The OPTN’s collection of data related to extra vessel(s) final disposition differs from solid organs due to timing of extra vessel(s) use and possible storage (i.e., extra vessels may be stored and used in a subsequent vascular reconstruction or organ transplant).

• The first important step in extra vessel data collection is when the OPO submits the donor organ disposition form (under feedback). This form indicates whether extra vessels were recovered and sent with an organ to a transplant center.

• When transplant centers remove an individual from the waiting list, they should indicate whether extra vessels were transplanted in the intended recipient or into a secondary recipient. If you aren’t sure of the extra vessel usage when you remove the recipient from the waitlist, we strongly recommend that you use the Vessel Use Report (utility) within the reports section of WaitlistSM to update the vessel usage status, as soon as possible.

• If extra vessels from multiple donors were used in the transplant procedure, please contact the UNOS Service desk at (800)-978-4334 to report additional donor IDs for the extra vessels transplanted.

• If you use stored extra vessels for vascular reconstruction in either the intended recipient or a secondary recipient, you must report this information by faxing or emailing the UNOS Data Quality department (this process is outlined in the OPTN Evaluation Plan – Vessel Transplantation/Destruction Information Sheet);

• UNOS strongly recommends that you report extra vessel disposition as soon as possible, either when extra vessels are transplanted or at least monthly, when they are discarded.

• Report any outstanding extra vessel(s) disposition immediately to the OPTN either through UNetSM (Vessel Use Report in WaitlistSM), or by fax/email.

• Do you need help reporting extra vessel disposition? Guidance for reporting extra vessels disposition is available on the UNOS member archive within the Policy Compliance/Patient Safety tab. Click here to access a guide for OPOs or transplant centers reporting extra vessel disposition to the OPTN: http://communication.unos.org/2011/09/guidance-for-reporting-the-final-disposition-of-extra-vessels/. Still have questions or concerns regarding vessel disposition reporting? Contact UNOS Data Quality at dataquality@unos.org or Regional Administration at (804) 752-4800.