Tissue Procurement, Storage, and Disposition

Purpose:
To provide guidelines for tissue procurement, storage and disposition at LSUHSC. All areas procuring, storing and dispensing tissue shall follow these guidelines as well as all unit/area specific policies.

Definitions:
Tissue specimens may include but are not limited to: bone, cornea, skin, heart valves/conduits, tendons, fascia, dura mater, bone marrow, veins, arteries, cartilage, sperm, embryos, eggs, stem cells, cord blood, synthetic tissue (artificially prepared, human and nonhuman based), and other cellular- and tissue-based transplant or implant products.

Policy:

1. The Transfusion Service has responsibility for oversight of the tissue program throughout the hospital.

2. The Transfusion Service will receive and maintain documentation regarding areas of tissue procurement, source facility, credentials of source facility, storage and coordinator of area and details of the recall process.

3. Units/area Procuring, Storing and Dispensing Tissue:
   a. Clinical Lab, Transfusion Service
   b. Bone Marrow Transplant Lab

4. All contracts for tissue shall require the supplier to notify The Safety Department and Transfusion Services of all tissue/organ recalls.

Procurement

All units/areas shall have qualified staff assigned to perform the following duties:

1. Validate that source facilities whom supply tissues are licensed by state agencies and/or registered as a tissue establishment with the Food and Drug Administration (FDA).

2. Transport, handle, store, and use tissue according to the source facilities’ or manufacturers’ written directions.

3. Verify at receipt that package integrity is met and transport temperature was controlled and acceptable.
4. Quarantine any tissue that does not meet requirements for transplantation and will notify source vendor.

Storage

1. Each unit/area shall maintain records documenting the source facility, the original numeric or alphanumeric donor and lot identification, all recipients or other final dispositions of each tissue, and expiration dates. Log in all incoming tissue including but not limited to date of receipt, description of tissue, and person completing log.

2. At the time of issuance for patient care, include medical record number, name of patient, date of use and other pertinent information based on unit/area specific policy.

3. These records are retained for a minimum of ten years beyond the date of distribution, transplantation, disposition, or expiration of tissue.

4. Maintain continuous temperature monitoring for storage refrigerators, freezers, and cabinets. Storage equipment must have functional alarms and emergency back up (exception: ambient storage cabinets).

5. Maintain daily records to show that tissues were stored at the required temperatures.

Main types of tissue storage are:
   a. “Ambient” room temperature (for example, freeze dried bone)
   b. Refrigerated (2-8°C)
   c. Frozen (<-40°C)
   d. Liquid nitrogen

Disposition

1. Documentation shall be made in the recipient’s medical record of tissue use, including documentation of the unique identifier of the tissue.

2. The Transfusion Service shall ensure that tissue information cards are returned to the source facility.

3. The Transfusion Service must maintain a detailed log containing information that allows LSUHSC-S to trace the tissue from the source to the patient and vice versa.

Recall

1. Tissue recall will be handled using Hospital Safety Department Recall Policy.

2. The Safety Department shall notify Transfusion Service, the Quality Leadership Team and the Infection Control Department of recalls or incidents of implanted tissue found to have HIV, HTLV-I/II, viral hepatitis, or other infectious agents known to be transmissible by tissue which are reported to them by the supplier or other entities.
3. The Safety Department will receive and maintain documentation of the recall process from all areas involved.

4. When discovered, each unit/area shall promptly report cases of post-transplant infections or adverse events first to Quality Management, Hospital Administration, Hospital Safety and Infection Control Departments. The source facility shall be notified by the direction of the Quality Leadership Team.

5. Each unit/area shall notify the Infection Control Department of adverse events (such as breaks in sterile technique), which occur at the unit level that may adversely affect the integrity or sterility of the implanted tissue.

6. Any notification to Infection Control from unit/area involved in recall or adverse event shall include all pertinent information including but not limited to: the patients name, medical record number or social security number, date of implantation, and the suspected disease process or infecting organism, or description of other adverse event.

7. The Infection Control Department will determine the length of follow-up, the scope of the epidemiologic investigation, surveillance techniques, and organizational reporting in accordance with LSUHSC-S Infection Control guidelines and nationally recognized guidelines. The Infection Control Committee, the Infectious Disease Department and Hospital Administration will be consulted as necessary for guidance in surveillance and reporting.

8. It is the responsibility of the Infection Control Department to investigate adverse events involving implanted tissue that either have contributed to an infection or may contribute to an infection in the future, and to report findings to the appropriate department managers, directors, hospital administration and chiefs-of-service.

9. All stored organs/tissues from donors that are recalled or found to be contaminated with HIV, HTLV-I/II, viral hepatitis, or other infectious agents should be retrieved and quarantined immediately, under the direction of the Safety Department. This tissue may only be used for research purposes, destroyed or returned for credit, except when transplantation of an indispensable organ/tissue is necessary to save a patients life.

10. Notification of recipients of tissue from donors who are subsequently found to have HIV, HTLV-I/II, viral hepatitis, or other infectious agents known to be transmissible by tissue shall be under the direction of the Quality Leadership Team. Recipients shall be informed of infection risk.

References:

AATB Standards

JCAHO Standards: TS.03.01.01, TS.03.02.01, TS.03.03.01

CDC Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs, MMWR 43 (RR-8); 1-17.


Administrator

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Date

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