Regulatory Compliance and Tissue Tracking

Presented by:
Victoria Steelman, PhD, RN, CNOR, FAAN

April 17, 2009
Overall, tissue transplantation is a safe practice in the U.S.

Infections
- 2001- musculoskeletal graft-associated infection lead to a 23 year-old’s death
  - Recovery processes violated national standards
- 14 other patients with allograft-related clostridium infections
  - Deviations from national standards
Recall of Human Tissue

DATE RECALL INITIATED:
   October 13, 2005

PRODUCT:
   Human Tissue for Transplantation

MANUFACTURER:
   Biomedical Tissue Services, Ltd
   Fort Lee, New Jersey

REASON:
   Biomedical Tissue Services (BTS) was recently made aware that there is the possibility that tissue has been procured from donors without proper medical/social histories. BTS is performing a voluntary recall of any unused tissue from its consignees.
Body parts harvested in N.C. are recalled
FDA won't say how many tainted parts sent to hospitals for transplant

AP  Aug 23, 2006
WASHINGTON - A leading medical firm has quietly recalled hundreds of human tissue products destined for transplants around the nation that were supplied by a North Carolina body parts broker believed to have a tainted history. The broker used an unsterile embalming room to carve up dozens of corpses to procure tissue, a Raleigh funeral home director said Tuesday. The U.S. Food and Drug Administration shut down the body broker on Friday, but refuses to say how many people may have received potentially risky tissue.
Regulations and Standards
Current FDA Regulations

- FDA 21 CFR 1270 Human Tissue Intended for Transplantation
- Screening and testing rules donors for hepatitis B and HIV
- Rules for record keeping
- Authority to inspect
- Authority to recall/destroy tissues
State Regulations

- New York
- California
- Florida
- Maryland
Tissue is Not a Surgical Supply
First Step: Determine Oversight

- Medical director
- Administrator
- Personnel
- Descriptions
  - Responsibilities
  - Training/competencies
Personnel

- Surgical tissue bank personnel must be knowledgeable about the aspects of tissue banking in which they participate.
  - Ongoing and continuing education provided
  - Focus on responsibilities
    - Ordering tissue
    - Receiving tissue
    - Storage of tissue
    - Release of tissue from tissue bank
    - Dispensing tissue onto sterile field
    - Preparing tissue for use
    - Return to tissue bank or disposal
    - Documentation/tracking
Facilities procuring, processing, and/or preserving tissue, and facilities storing tissue for potential transfer to different facility, must register as tissue banks with the FDA.

Exemptions

- Cranial bone flaps
- Autograft skin
- Only purchased tissue
Tissue Bank Selection Criteria

- Develop criteria for selecting a vendor of tissue
Selecting a Tissue Bank

- AATB accreditation status
- FDA registration
- State registration
- ISO certification
- Surgeon preference
- Type of processing

- Quality of tissue
- Availability of tissue
- Safety track record
- Clinical results
- Processing fees
- Packaging
- Customer service
Tissue Tracking

- From donor to recipient
- From donor to disposition
Receipt of Tissue

- Record receipt, including unique identifiers, expiration date, identification of person accepting tissue, date & time.
- Verify that the package integrity was maintained during transport & that the expiration date has not been exceeded.
- Document the recommended temperature.
- For tissue requiring controlled storage, verify that the recommended temperature was maintained during transport.
  - Validated shipping container is undamaged and within the validated timeframe.
  - Presence of any remaining regular or dry ice
  - Taking the temperature in the center of the product, or using a commercial shipping temperature indicator.
  - Not required for ambient temperature
Storage

- Transfer to storage in a manner consistent with the source facility’s written instructions.
- Tissue stored in a secure area, with access restricted to authorized personnel.
- AATB recommendations for storage temperatures, durations
  - Monitored for refrigerated, frozen, or if manufacturer gives a temperature range
  - TJC does not require for ambient temperature
- Freezers - monitor & alarm
- Have a backup plan for freezer failure/cleaning
Storage Temperatures

- **Lyophilized or dehydrated musculoskeletal tissue**
  - ambient temperature or cooler (but not frozen) 68-77 °F

- **Refrigerated musculoskeletal and osteoarticular tissue**
  - 33.8° F (1° C) to 50° F (10° C).

- **Refrigerated skin:**
  - 33.8° F (1° C) to 50° F (10° C).

- **Frozen musculoskeletal & osteoarticular tissue:**
  - –40° F (–40° C) or colder for long-term storage
  - –20° C to –40° C for short-term storage (less than 6 months).

- **Frozen or cryopreserved skin**
  - –40° F (–40° C) or colder.
Transportation

- Tissue is transported and stored in a manner to minimize the risk of compromise or contamination.
  - Containers for transportation must protect tissue from contamination
  - Maintain temperature of frozen and refrigerated tissue- validated containers
Recipient Rights

- Potential recipients of tissue should be treated with respect, dignity, and sensitivity, and their rights should be protected.
  - Discussion of risks, benefits, and alternatives
  - Informed consent
Preprocedural Time Out

Verify the availability of

- Relevant documents, such as the history and physical, pre-anesthesia assessment
- Accurate, complete, and signed procedure consent form*
- Correct and properly labeled diagnostic and radiology test results
- Any required blood products, implants, devices or special equipment
Reconstitution

- Allograft tissue obtained from an outside tissue bank should be handled in a manner consistent with the source facility’s or manufacturer’s written instructions.
- Written instructions should be maintained for each tissue implanted.
Policies and Procedures

- **Readily available in the practice setting.**
- **Reviewed annually**
  - Authority, accountability, oversight
  - Criteria for selection of tissue banks
  - All steps of process
  - Approval of release of tissue for implantation by responsible authority
  - Receiving, storing, and handling tissue
  - Criteria for returning tissue to storage
  - Adverse tissue reactions and recall procedures
Adverse Tissue Reaction Policies

- Reporting: Facility to the patient
- Reporting: Patient to donor source
- The Joint Commission. Adverse tissue reaction policies (12/24/08)
  - [http://www.jointcommission.org/AccreditationPrograms/Office-BasedSurgery/Standards/09_FAQs/PC/Adverse_Tissue_Reaction.htm](http://www.jointcommission.org/AccreditationPrograms/Office-BasedSurgery/Standards/09_FAQs/PC/Adverse_Tissue_Reaction.htm)
Recordkeeping

- Each tissue bank must maintain donor, tissue, and recipient records to ensure that pertinent data are retrievable.
  - Log of all tissues ordered, received, stored, implanted, discarded
  - Ordering
  - Receipt
    - Packaging integrity, temperature controlled & acceptable, instructions, date, time, person accepting
  - Dates, times of issuing from the tissue bank
  - Dates, time, methods, and person overseeing preparation of tissue for use
    - Source manufacturer’s instructions
  - Patient identification
  - Disposal of tissue

- Maintain for 10 years
Quality Management

- Must be in place to evaluate the structure, processes, and outcomes of tissue bank services.

  - **Structure**
    - Training and competencies of personnel
    - Criteria for selection of tissue banks
    - Copies of registration, certifications of sources

  - **Records**
    - Traceability from source to donor
    - All steps of processes used
    - Package integrity verified upon receipt
    - Transport temperature controlled and acceptable

  - **Adverse tissue reactions and recalls**
Managing a tissue recall in a large academic hospital

Victoria M. Steelman and Annette J. Schlueuter

BACKGROUND: In October 2006, a recall of human tissue for implantation was initiated because one recovery center obtained tissues from donors who were not screened properly for infectious diseases. The Food and Drug Administration (FDA) and Centers for Disease Control (CDC) recommended notifying affected patients and offering access to infectious disease testing. 

STUDY DESIGN AND METHODS: A multidisciplinary team was established to provide a framework for responding to the recall. The plan was designed to meet six goals: Steps included patient identification, surgeon and patient notification, patient education and testing, communication of test results, and information for the public.

RESULTS: The institution recalled 300 tissues, of which 48 had been implanted into 30 patients undergoing neurosurgical, orthopedic, and general surgical procedures. Patients were identified and sent notification letters within 2 weeks of the FDA and CDC recommendations. Twenty-seven patients underwent testing, which was performed at the convenience of the patients at no cost to them. One patient had evidence of previous (but not current) hepatitis B infection. Overall, patients were appreciative of the processes used. Media coverage was positive.

CONCLUSION: The response plan was generally successful in achieving the established goals. Potential improvements were identified in several areas, including initial patient notification and coordination of test result communication. It is critical to allow flexibility to meet each patient's needs. The plan may serve as a template for use in future tissue recalls by other hospital-based tissue banks.

The transplantation of human tissue carries a inherent risk of infectious disease (ID) transmission. This risk is minimized through regulations of the Food and Drug Administration (FDA), including registration of tissue banks, donor suitability criteria, and good manufacturing practices, and by standards of the Joint Commission for Accreditation of Hospital Organizations (JCAHO) and American Association of Tissue Banks. These regulations and standards, however, may be violated. When errors are identified, the potentially compromised tissue is recalled. Hospital-based tissue banks must rapidly respond to these recalls. This article describes the complex tissue recall process in a large academic hospital and the lessons learned from this process.

In October 2006, hospitals across the United States were notified that tissue procured by Biospecimen Tissue Services (BTS) was being recalled. The recall initially involved 300 tissues procured by BTS that was subsequently processed and distributed by LifeCell Corp. (Branchburg, NJ) and was based on concern about the authenticity of donor screening records supplied by BTS (letter from B. Lamb, Senior Vice President of LifeCell, to LifeCell customers, October 12, 2006, and Recall of Human Tissue Products). Ten to 14 days later, three other tissue banks that distributed tissue obtained from BTS also initiated recalls. These were Lost Mountain Tissue Bank, The Blood and Tissue Center of Central Texas, and Tissuegen. On October 13, BTS initiated a recall followed the next day by a recall from a major distributor of musculoskeletal tissue.

ABBREVIATIONS: APN = Advanced Practice Nurse; BTS = Biospecimen Tissue Services; ID = infectious disease.

From the Department of Nursing Services and Patient Care, The University of Iowa Hospitals and Clinics, Iowa City, and the College of Nursing, and Department of Pathology, Carver College of Medicine, The University of Iowa, Iowa City, Iowa. 
Address correspondence to Annette Schlueter, M.D., Ph.D., Department of Pathology, University of Iowa, CB265 (14, 300 Iowa Ave., Iowa City, IA 52242); e-mail: annette.schlueter@uiowa.edu.

Received for publication September 29, 2006; revision received October 18, 2006, and accepted October 26, 2006. doi: 10.1111/j.1537-2995.2007.00332.x

TRANSFUSION 2007;47:927-934.

Volume 47, May 2007 TRANSFUSION 927
Summary

- Tissue is not a medical supply!
- Tissue banking includes use of purchased tissue.
- Implement a structure with clear accountability to maximize safety.
- Follow the manufacturer’s instructions for storage, handling, and preparation of tissue.
- Maintain adequate records of ordering, receipt, storage, transplant, and disposal.
- Include a quality management program with adverse tissue reaction policies.
References


- American Association of Tissue Banks, Standards for Tissue Banking, 10th ed (McLean, VA: American Association of Tissue Banks, April 2002).


