Top 10 Facts:

To Know About
A Centralized Tissue Service within the Hospital Blood Bank

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Objectives

- To understand how hospital tissue services work to ensure safe tissue practices

- Discuss the challenges and successes using a centralized tissue management model within a blood bank environment

- Identify the process for meeting regulatory requirements for hospital tissue services in a centralized model
Tissues are as highly regulated as blood & blood products.

**FDA Regulation**

May 25, 2005

- FDA establishes regulations for human cells, tissues, and cellular and tissue-based products (HCT/Ps)

Registration definition: Establishments involved in the production and distribution of medical devices intended for marketing or leasing (commercial distribution) in the United States (U.S.) are required to register with the FDA. This process is known as establishment registration. Registration provides FDA with the location of medical device manufacturing facilities and importers. The regulations for establishment registration are provided in [21 CFR 807].

No registration fee is required.
The Joint Commission (TJC) Requirements

New Emphasis

Traceability and Reporting and Investigating Infections

The Joint Commission on Accreditation of Healthcare Organizations

The Joint Commission evaluates and accredits more than 15,000 health care organizations and programs in the United States.

An independent, not-for-profit organization, the Joint Commission is the nation's predominant standards-setting and accrediting body in healthcare.

Mission: To continuously improve the safety and quality of care provided to the public through the provision of healthcare accreditation and related services that support performance improvement in health care organizations.
Transplant Safety Standard
The organization uses standardized procedures to acquire, log in and store tissue. The intent is that the organization:

Assigns responsibility for handling the tissue program
(including storage, issuance)

Validates supplier is registered with FDA

Coordinates ordering and storage [emphasis added] throughout the facility

Conforms transportation and storage to the source facilities' written directions;

Logs all incoming tissue; and

Has temperature monitoring for storage refrigerators and freezers, alarms, and emergency back-up as required.

Main types of storage used are room temperature, deep freezing colder than -60ºC, and liquid nitrogen

Transplant Safety Standard

The organization's record keeping permits the traceability of all tissues. The intent is that the organizations’ records:

Permit tracing of any tissue from the donor or source facility to all recipients or other final dispositions;

Identify the staff involved in preparation or issue of tissue, who accepts the tissue, and the dates involved;

Include documentation of tissue use in the patient’s clinical record;

Returns Tissue Use Form to supplier

Include storage temperatures, control testing, and all superseded procedures, manuals and publication, and are retained for a minimum of 5 years, or as required by applicable state and federal laws; and

Document the source facility, the original numeric or alphanumeric donor and lot identification, and all recipients or other final dispositions of each tissue. These documents are retained indefinitely.
Transplant Safety Standard

Has procedures to promptly investigate adverse events, disease transmission to tissue recipients (both discovered in recipients or from notification by supplier)

Report infections to supplier

Sequester tissue if supplier reports possible contamination.

Inform recipient if supplier later reports donor infections

Largest Nationwide Tissue Recall Ever

October 2005

FDA Orders Biomedical Tissue Services (BTS) to Cease Manufacturing and to Retain Existing Inventories of Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps)
Blood bankers possess the expertise to manage tissues similarly to blood products.

Why is the blood bank talking about storing tissues?
The tedious & cumbersome issues of inventory management for surgery departments have been alleviated by more efficient tracking methods of blood banks.

Blood Bank Model

Blood transfusion traceability from Donor vein to Recipient vein:
- Blood donor center to hospital
- Hospital blood bank records and patient records permit tracing
Tissue allograft traceability from Deceased donor to Allograft recipient

Tissue procurement agency (tissue bank/OPO etc) to
Tissue processing facility (tissue bank) to
(Sometimes to tissue broker/distributor) to
to hospital, surgicenter, dentist office

Tissue Bank Assures Traceability & Trackability

<table>
<thead>
<tr>
<th>Tissue Bank Standard Operating Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Receipt – Visually inspected, electronically entered into LIS, assigned unique identification number, and placed in monitored storage</td>
</tr>
<tr>
<td>Tissue Product Order Entry – Tissue Products allocated electronically to patients similarly to the process used for manufactured products</td>
</tr>
<tr>
<td>Tissue Product Issue – Tissue Products issued electronically and physically using the same “read back and verified” procedures required for blood components</td>
</tr>
<tr>
<td>Tissue Product Return – storage conditions must meet manufacturer’s recommendations during permanent and temporary storage. Products status updated electronically in the LIS</td>
</tr>
<tr>
<td>Tissue Bank assumes responsibility for returning manufacturers’ implantation records</td>
</tr>
</tbody>
</table>
Centralized Tissue Bank Process

- Use of laboratory information system (LIS) or free standing inventory management program for track and traceability purposes
- Codes can be programmed into LIS or use of codes from free standing systems can be used to create labels for each product brought into inventory (original label is never obscured)
- Monitor, allocate, and issue tissue in a similar process to blood products

Labeling of Tissues by Hospitals

- Labeling for unique identifiers in hospitals
- Cataloging tissues for communication purposes between OR staff and Blood and Tissue Bank staff
Tissue Bank
good stewards for other
CHOA Cost Centers

Cost Containment Savings
Contractual Agreement revised
from Consignment to Direct
Purchase

Tissue Bank Serves
Multiple Cost Centers

Egleston Campus

Tissue Bank Orders ↔ OR Cost Center

Scottish Rite Campus

OR Cost Center ↔ Tissue Bank Orders

Meridian Mark Satellite Cost Center
Blood bankers possess knowledge of the infrastructure & experience in a heavily regulated environment necessary to manage tissues.

**Staffing Infrastructure**
- MD medical director
- Blood and Tissue Bank Manager
- Tissue Coordinator
- Tissue Technologist
- All blood bank staff
Hospital Tissue Bank Transformation

Regulatory Agencies

- Food and Drug Administration (FDA)
- The State Agency
- The Joint Commission (TJC)
- Eye Bank Association of America (EBAA)
- American Association of Blood Bank (AABB)
- American Association of Tissue Banks (AATB)
- College of American Pathologists (CAP)

Decentralized to Centralized Hospital Tissue Banks
Facilities Expansion At Children’s Healthcare of Atlanta

Both campuses at Children’s Healthcare of Atlanta expanded their physical space to accommodate for tissue refrigerators, freezers, room temperature monitoring devices, and liquid nitrogen tank storage.

Tissue Coordinator and Technologist Work Space Contiguous with Blood Bank
# 5

Inadequate storage conditions for tissues have been replaced & are accurately met in blood banks.
Room Temperature Storage

Liquid Nitrogen Tank Storage for Cardiovascular Surgery Homografts
Blood banks follow vendor qualification & validation processes more stringently as required.

Centralization Tissue Bank Process

- Create requisition forms and pick up slips
- Train nurses and medical technologists in blood bank
- All inventory ordering is done by tissue bank with the teamwork of nursing and physicians in each tissue program
- Redirect supply chain (purchasing) to have all inventory shipped directly to blood bank
- Vendor qualification performed on each tissue supplier
Handling New Tissue Product Requests

- Establish committee with peer group of surgeons and personnel from supply chain (purchasing)

- Criteria for acceptance/denial of new products should be established: (i.e. scientific evidence of effectiveness, vendor is qualified, no duplication of product already in inventory)
Homograft Tissue Requisition Form

CHOA Tissue Product Release Form
Tissue Transport Log

Tissue Inventory Form
Oversight by a single blood bank medical director confers greater uniformity and conformity.

All Tissue is not Created Equal

Examined individual needs of each program and tailored them to fit expectations of the surgeons/nurses/tissue bank technologists and remain in regulatory compliance.
Specific Tissue Programmatic Needs

- Cardiovascular surgery and homografts allocation, issuing

- Ophthalmologic surgery and corneal transplantation program

Scope of Tissue Use

- Allogeneic tissue primarily
  examples: frozen, room temp, refrigerated, freeze dried

- Capability of autologous procurement
Staff of Tissue Bank involving Tissue Bank Medical Director

- Handling of recalls or market withdrawals of tissues
- Investigating potential infectious and non-infectious adverse events
- When problems arise between surgeon or OR nurses and tissue bank staff due to timeliness of receiving grafts on days of surgery, advance ordering, and paperwork completion
- Approval of new products requested by surgeons

What we found helps to promote a successful transition of tissue bank programs into blood bank

Teamwork and Collegiality between medical technologists and surgical nurses and physicians
# 8

Greater compliance in investigating & reporting of tissue adverse events (infectious/mechanical) is being appropriately met by blood banks.

**Investigating Suspected Adverse Events**

- Sequester unused tissue derived from same donor or lot
- Notify hospital tissue service medical director
- Create adverse event file
- Notify tissue processor (listed in package insert) and tissue supplier (if not the same)
- Confirm type and severity of infection in patient
- Investigate as possible nosocomial infection
- Investigate if patient has other risk factors for infection
Investigating Suspected Adverse Events

- Examine hospital tissue service and operating room records for breaks in procedures
- Conduct sentinel event-type root cause analysis
- Cooperate with investigation conducted by tissue supplier
- Arrange for testing of unused allografts and other recipients of allografts derived from same donor, if appropriate
- Implement corrective actions, if appropriate
- Report investigation results
- Place copy of investigation summary in tissue supplier’s vendor qualification file

# 9

Cost savings & potential earnings are a likely consequence of tissue management in blood banks.
Tissue Utilization Statistics for Tissue Transplantation Committee

- Statistics for tissue/transfusion committee
- Tissue Issued per service per week
- Total tissue issued per month
- Tissue transplanted/returned

Scottish Rite Tissue Totals

- Total Tissues Ordered
- Total Tissues Implanted
- Total Tissues Return to Inventory
- Linear (Total Tissues Ordered)
Pre ordering by SRH OR

- June 2011, 192% increase in tissue products implanted over average
  - Increase usage anticipated by the Tissue Bank

- Lifelink backordered on 90ml, 4-10 mm cancellous bone
- Obtained product from MTF
  - Tissue Bank able to fill all orders

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**Egleston Tissue Totals**

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<thead>
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<th>Count</th>
<th>J-10</th>
<th>M-10</th>
<th>M-10</th>
<th>J-10</th>
<th>J-10</th>
<th>S-10</th>
<th>S-10</th>
<th>N-10</th>
<th>N-10</th>
<th>J-11</th>
<th>J-11</th>
<th>M-11</th>
<th>M-11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Tissues Ordered</td>
<td>78</td>
<td>57</td>
<td>58</td>
<td>69</td>
<td>73</td>
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<td>13</td>
<td>9</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>Total Tissues Implanted</td>
<td>21</td>
<td>21</td>
<td>18</td>
<td>21</td>
<td>14</td>
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<td>5</td>
<td>9</td>
<td>9</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Total Tissues Return to Inventory</td>
<td>21</td>
<td>18</td>
<td>21</td>
<td>21</td>
<td>14</td>
<td>19</td>
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<td>9</td>
<td>5</td>
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<td>9</td>
<td>13</td>
<td>13</td>
</tr>
</tbody>
</table>

Legend:
- Total Tissues Ordered
- Total Tissues Implanted
- Total Tissues Return to Inventory
- Linear (Total Tissues Ordered)
Overall improvement of tissue management in hospital blood banks will assure & enhance patient safety.

Top 10

1. Tissues are as highly regulated as blood & blood products.
2. Blood bankers possess the expertise to manage tissues similarly to blood products.
3. The tedious & cumbersome issues of inventory management for surgery departments have been alleviated by more efficient tracking methods of blood banks.
4. Blood bankers possess knowledge of the infrastructure & experience in a heavily regulated environment needed to manage tissues.
5. Inadequate storage conditions for tissues have been replaced & are accurately met in blood banks.
Top 10

6. Blood banks follow vendor qualification and validation processes more stringently as required.

7. Oversight by a single blood bank medical director confers greater uniformity & conformity.

8. Greater compliance in investigating and reporting tissue adverse events is being appropriately met by blood banks.

9. Cost savings and potential earnings are a likely consequence of tissue management in blood banks

10. Overall improvement of tissue management in blood banks will assure & enhance patient safety.

Quiz

1. Centralized tissue banks within a hospital blood bank are able to manage inventory by:
   A. Use of a free standing inventory management program
   B. Adaptation of their laboratory information system to accommodate tissue and blood products
   C. Neither
   D. Both A and B

2. All of the following steps are appropriate for a hospital tissue service to execute while investigating a suspected adverse event except:
   A. Sequester unused tissue derived from same donor or lot
   B. Confirm type and severity of infection in patient
   C. Notify hospital tissue service medical director
   D. Optional notification of tissue processor (listed on package insert) and tissue supplier (if not the same)
Thank you!!