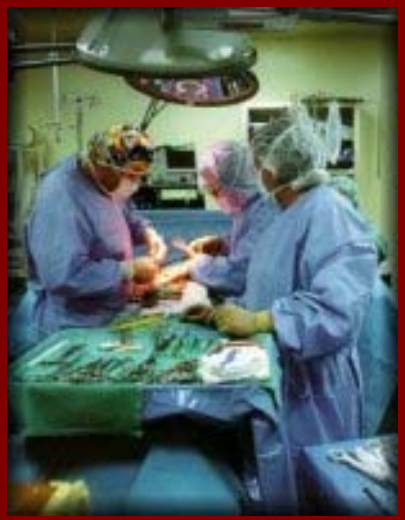
Hospital Handling of Tissues: Tissue Safety and Comparison to the blood transfusion service model



ACBSA May 11 2007

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PAGE 612 899 2449

Plan to discuss……..

Similarity between organ, tissue, blood transplantation

Clinical Use and Risks of Tissue Allografts

- **Infectious diseases transmitted by tissue allograft use. (cases and lessons learned)**

Hospital handling of tissues: basic elements and issues

- **Lack of 100% reliable traceability, Inability to find patients who received infected allografts**
- **Lack of centralized responsibility**
- **Suboptimal investigation of adverse outcomes**
- **Lack of medical overview**

Improvements:

- **STANDARDS: AABB, AATB, JCAHO(TJC), EBAA, AORN.**
- **Recent Improvements since 2005 (TJC standards)**
- **AABB Tissue Committee efforts**
- **Increased numbers of hospital blood banks handling tissues**

Answers to Questions

Basic similarities between organ, tissue blood donations and use:

PUBLICLY DONATED RESOURCE, INFECTIOUS RISK, PERISHABLE SHORT-LIVED STORAGE

Organ Transplantation	Donor Suitability	Procurement	Processing	Storage	Clinical Use
Tissue Transplantation	Donor Suitability	Procurement	Processing MFG QC	Storage	Clinical Use
Blood Transplantation	Donor Suitibility	Procurement	Processing MFG QC	Storage	Clinical Use

Public support, donor recruitment, donor screening exam & testing Hospital blood bank model includes: Investigation of adverse outcomes, recalls, lookback investigations. Medical director overview. Peer physician overview (unclear for tissue).

Basic Steps From Donor to Recipient
Blood & Tissue Supplier, (manufacturers)

BLOOD CENTER
DONOR SUITABILITY

- Voluntary donation
- Med Hx, Soc Hx, risk factor exclusions
  - Perm exclusion MSM, IDU
- Physical exam (temp, pulse, BP, IDU track marks)
- Confidential exclusion
- Aseptic collection
- Donor callback
- Infect Disease Tests

……

MFG

- Component prep, processing
  - Leukoreduction
  - Bacterial testing
- Storage, distribution

……

- Adverse reaction evaluation
- Initiate recalls and lookback investigations

TISSUE BANK
DONOR SUITABILITY

- Voluntary donation
- Med Hx, Soc Hx, risk factor exclusions
  - 5 yr exclusion MSM, IDU
- Physical exam (more extensive)

- Aseptic collection
  - Bacterial testing
- Infect Disease Tests
  - Includes HCV RNA, HIV RNA
- Autopsy

……

MFG

- Component prep, processing
  - Disinfection
  - Sterilization
  - Bacterial testing
- Storage, distribution

……

- Adverse reaction evaluation
- Initiate recalls and lookback investigations

Basic Steps From Donor to Recipient
Handling Blood & Tissue in Hospitals

Blood Transfusion Service

- Vendor Qualification
- Incoming inspection , log in
  - Retest ABO,Rh
- Storage
- Recordkeeping
- Matching, selection
- Release from storage
  - Glucose test platelet conc

- Preparation
  - Thawing, pooling
- Administration
  - Infusion
- Investigate adverse outcomes
  - After nurse or MD reports
- Conduct recalls
- Conduct lookback investigations
  - CFR specifies details for HIV, HCV including numbers of attempts, timelines

Hospital Tissue Service

- Vendor Qualification
- Incoming inspection , log in

- Storage
- Recordkeeping
- Matching, selection
- Release from storage

- Preparation
  - Thaw, reconstitute
- Administration
  - Implant
- Investigate adverse outcomes*
  - After MD reports
- Conduct recalls*
- Conduct lookback investigations*

*weakest activity

Transmission of Disease

Blood Transfusion	Tissue Transplantation	Organ Transplantation
HIV, HBV, HCV,	HIV, HBV, HCV,	HIV, HBV, HCV,
CMV	CMV	CMV
Bacteria	Bacteria	Bacteria
?CJD	CJD	CJD
……	……	……
West Nile Virus		West Nile Virus
Toxoplasmosis		Toxoplasmosis
Parvovirus		Parvovirus
Chagas		Chagas
Malaria		Malaria
GVHD		GVHD
……	……	……
	Rabies	Rabies
	Malignancy	Malignancy
	Tuberculosis	Tuberculosis
	Herpes simplex	Herpes simplex
……	……	……
Babesiosis	Yeast	HHV-8, EBV
Colorado tick fever	HTLV	Lymph Choriomeningitis virus
RMSF		Strongyloidiasis
		Sarcoidosis

Prevalence of tissue allograft-associated infections

……..

Low but Unknown

……..

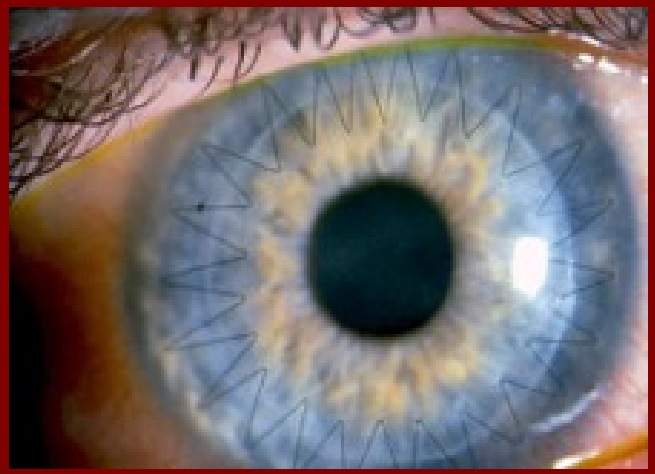
Retrospective and prospective studies needed

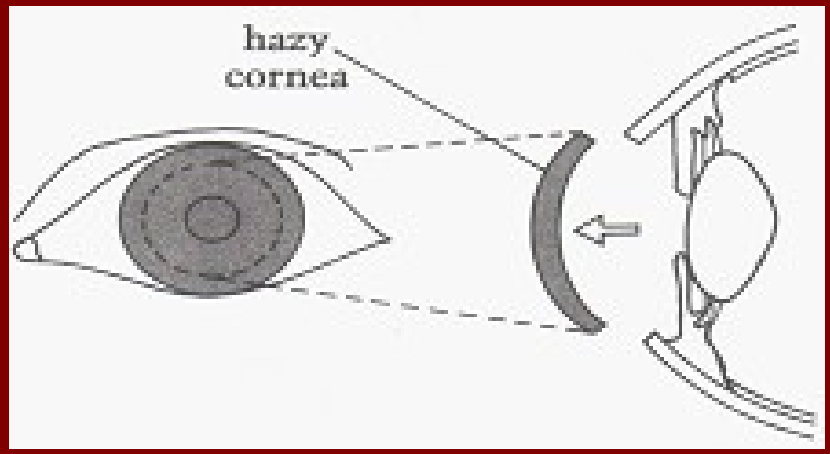
Studies needed about source of bacterial contamination

(e.g., bacterial translocation from GI to blood and tissue immediately after death)

Common clinical uses of tissue allografts

Infectious complications



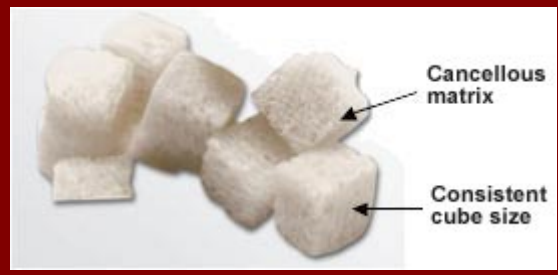


~50,000 corneal transplants/year in US

Viable, refrigerated storage

Diseases transmitted:
bacteria, fungus,
hepatitis B virus,
rabies, CJD,
malignancy

Common uses



Bone:

Hip revision arthroplasty

Spine fusion

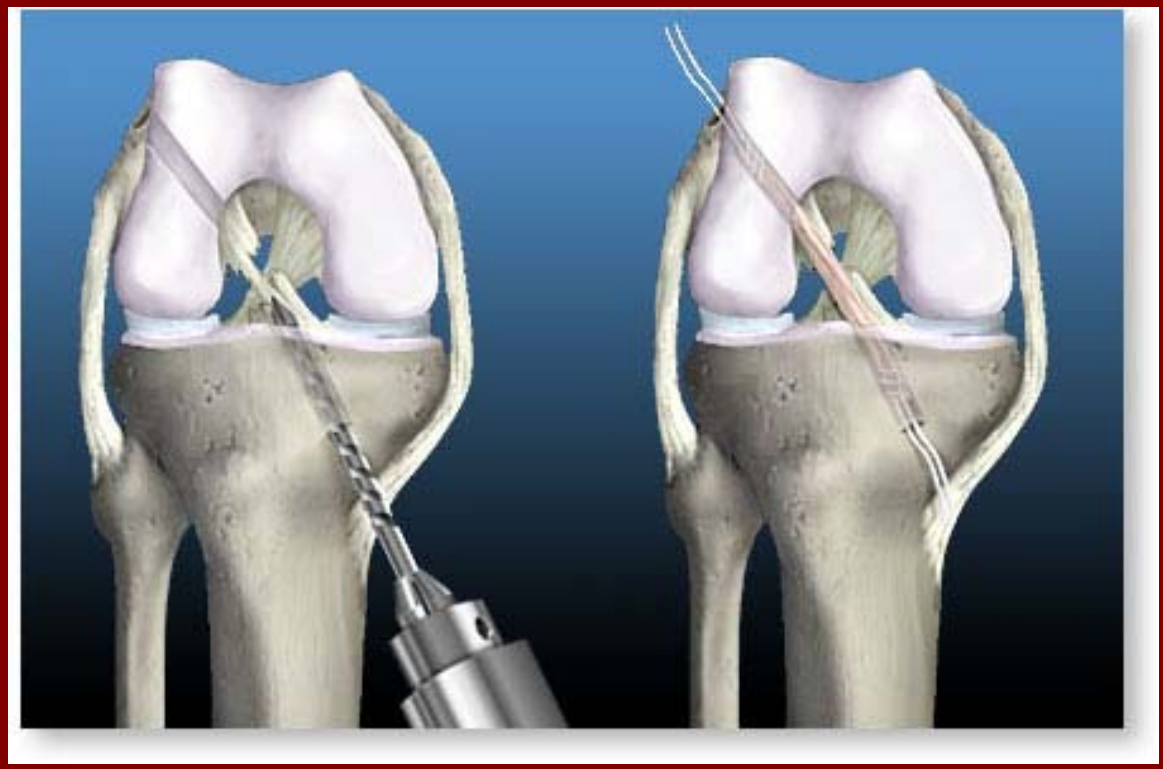
Fracture nonunion

Dental:

Periodontal defects (bone powder)

.....

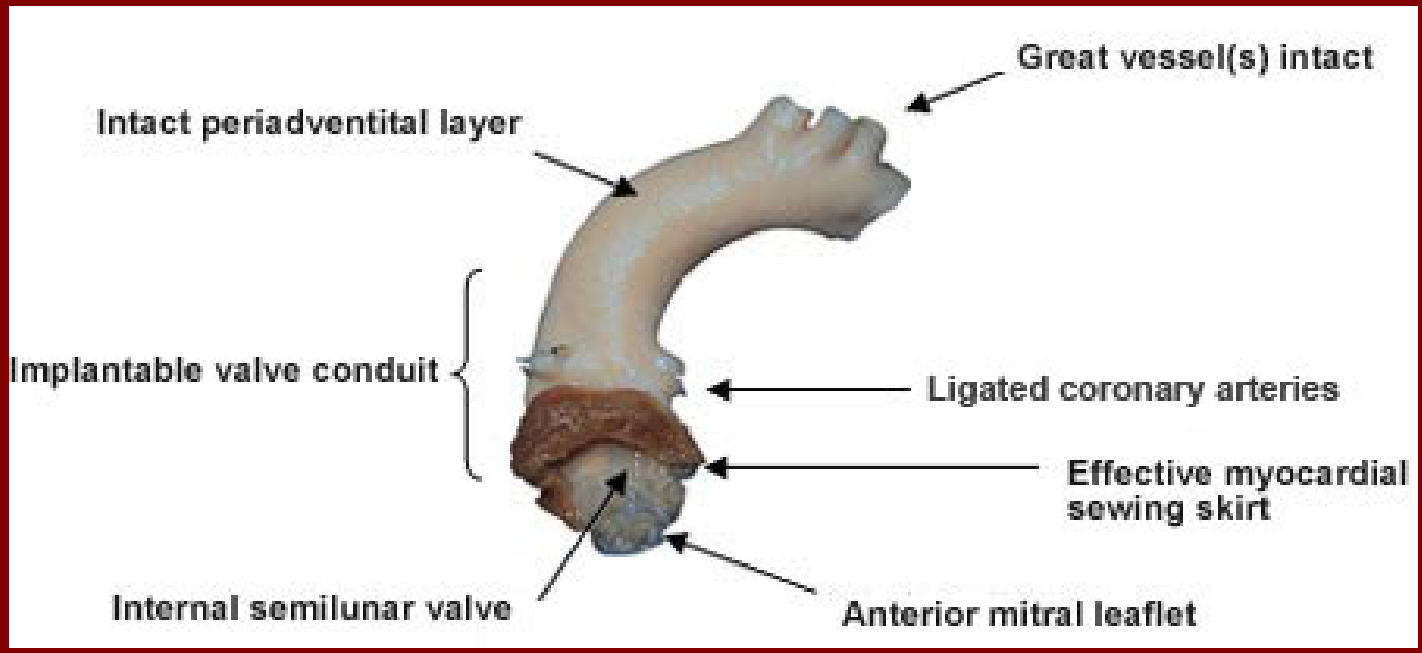
Diseases transmitted: HIV, HCV, HTLV, tuberculosis, bacteria

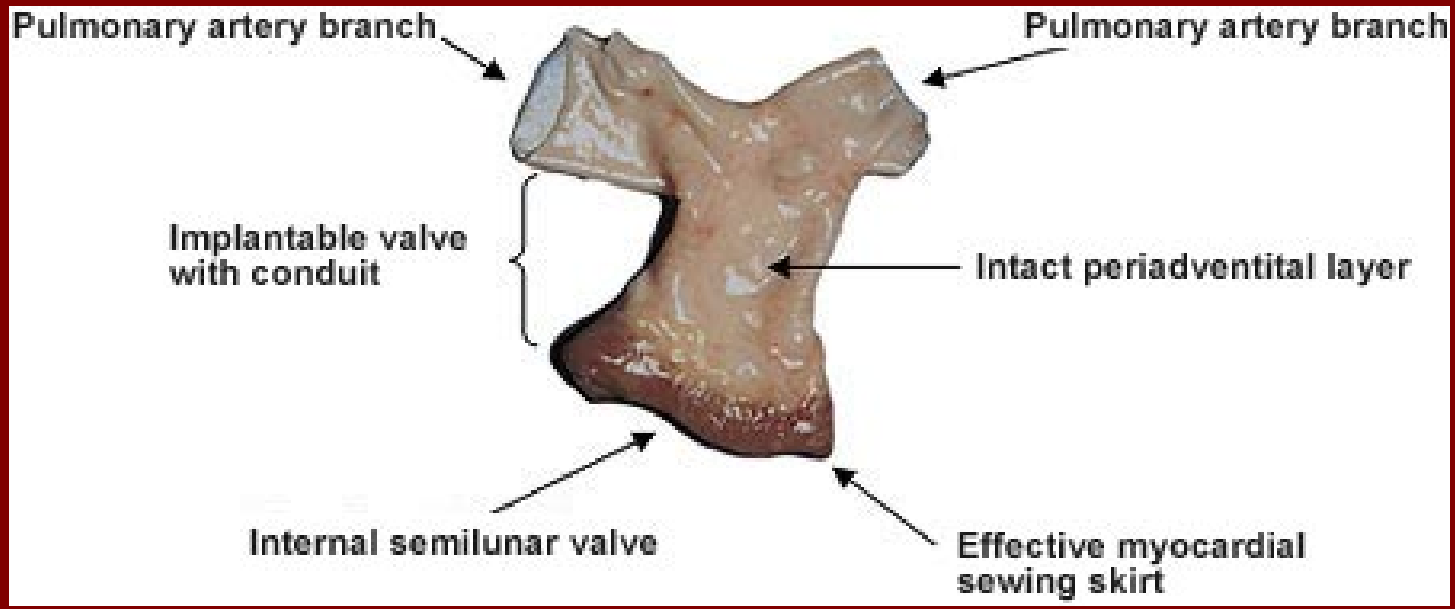


Tendon allograft

for repair of torn anterior cruciate ligament

Diseases transmitted:
HIV, HCV, Bacteria





Frozen Heart valve Allografts

(better than mechanical, biomechanical)

~7000/yr In US

(liquid nitrogen storage, viable)

Diseases transmitted:

Bacteria
Yeast
?TB
?hepatitis

DISEASES TRANSMITTED BY Other TISSUES

Cartilage

Bacteria

Skin	Pericardium	Dura	Vessel
Bacteria	Bacteria	CJD	HCV
HIV			Rabies
? CMV			

Allograft characteristics affecting ability to transmit disease

- Nonviable Allograft
  - Bone
  - Costal cartilage
  - Dura mater
  - Fascia
  - Ear ossicles
  - Tendon
- Non-viable Acellular
  - Connective tissue
- Can be disinfected, processed, sterilized

Viable Allograft

-- Heart valve and vessels (?)

- Cornea
- Articular Cartilage
- Skin
- Marrow
- Blood stem cells

- Contains viable cells
- May be antibiotic treated
- Cannot be sterilized

Sources of Infections Transmitted by Tissue Allografts from Deceased Donors

- Newly Infected donor
  - Sero negative window
    - HCV: frozen bone, frozen tendons & saphenous vein*,
    - HIV : frozen bone & tendon
  - Wrongly diagnosed but systemic acute illness in symptomatic donor
    - Grp A Streptococcus Toxic shock syndrome: frozen tendon*
    - Rabies: fresh cornea, fresh artery*
    - CJD: dura, fresh cornea

* Occurring or reported in 2002, 2003, 2005

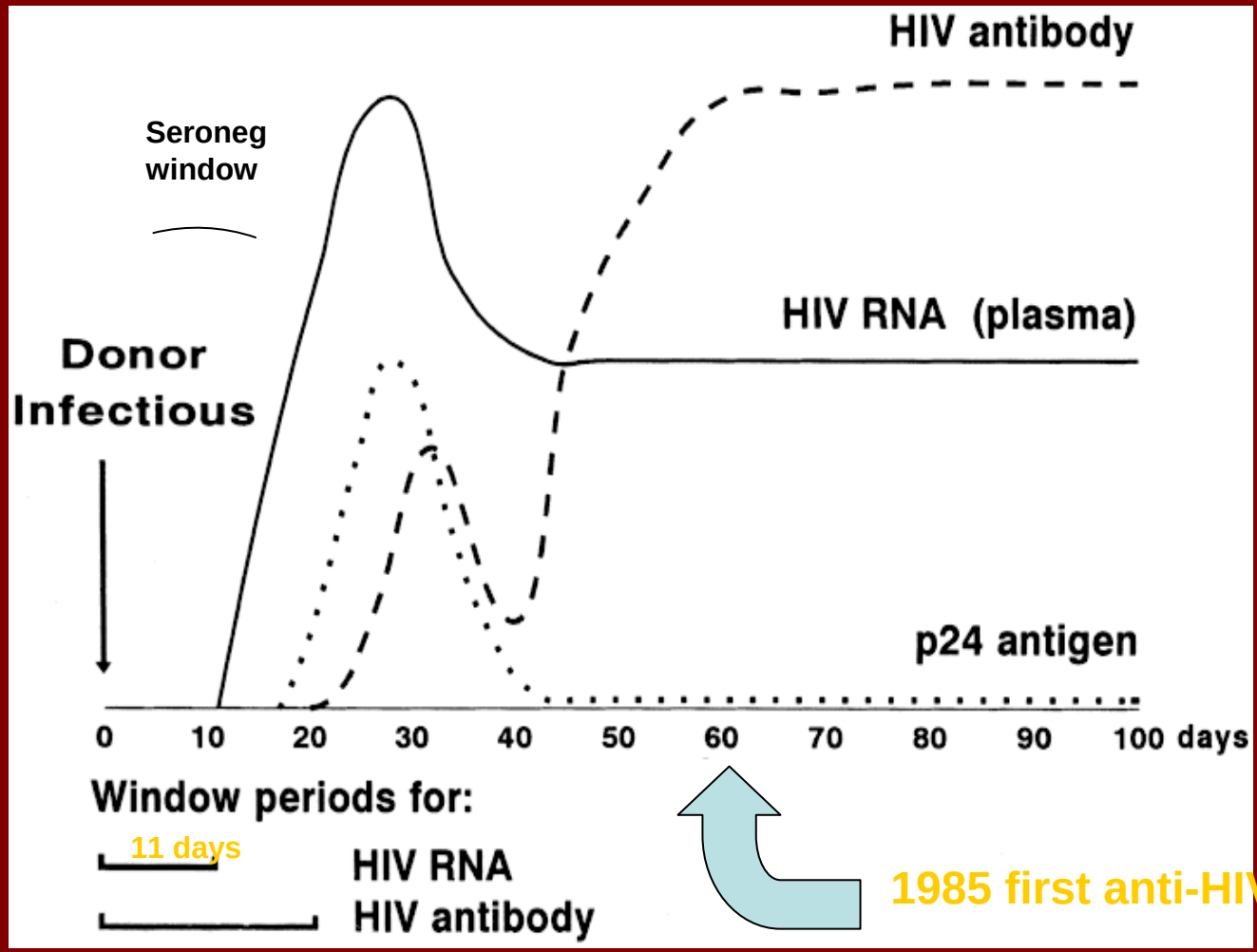
Old HIV & Recent HCV case demonstrates

- **Risk of Seronegative early infection in donor**
  - **(now deceased tissue donors are tested for HCV RNA & HIV RNA)**

Also demonsrates

- **Incomplete investigations of reports of HCV infection in organ, tendon and vein recipients**
  - **Organ recipients infected,**
  - **Tibial tendon, vein recipient infected**
    - **Was hospital notified?**
    - **Tissue bank was notified but concluded HCV not from donor without an real investigation**
- **Lack of communication to other tissue bank who obtained tissue from same donor**
- **Lack of ability to identify, notify and test all the other recipients of tissue from same infected donor**
  - **hospital recordkeeping, traceability failure**
  - **no longer as big a problem as it was in past**

Appearance of HIV antigens and antibodies after infection



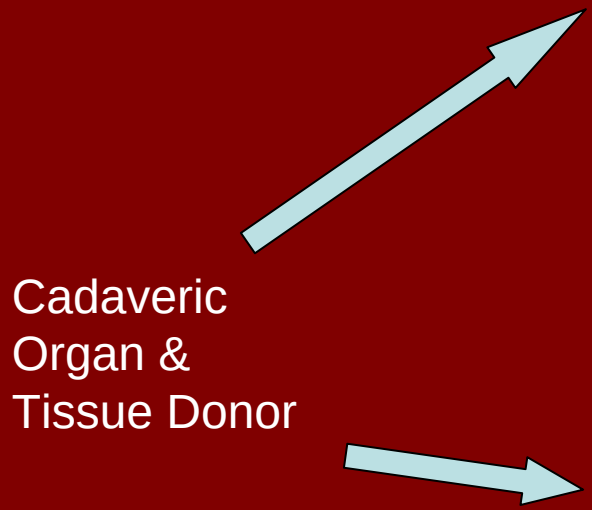
HIV from organ and tissue donor 1985

- Transmitted by organs, unprocessed frozen tendon, two unprocessed frozen femoral heads,
- Not transmitted by freeze-dried tendon (blood, cells removed from bone ends, antibiotic soaked), freeze-dried bone (blood, cells removed, ETOH soaked) or irradiated dura

- **Six recipients not able to be identified by hospitals during epidemiologic investigation in 1991**.
  - Inadequate hospital recordkeeping!

Simonds et al NEJM 1992;326:726

HCV Transmission by Organ & Tissue Allografts From a Seronegative Donor (anti-HCV NEG, HCV RNA POS)



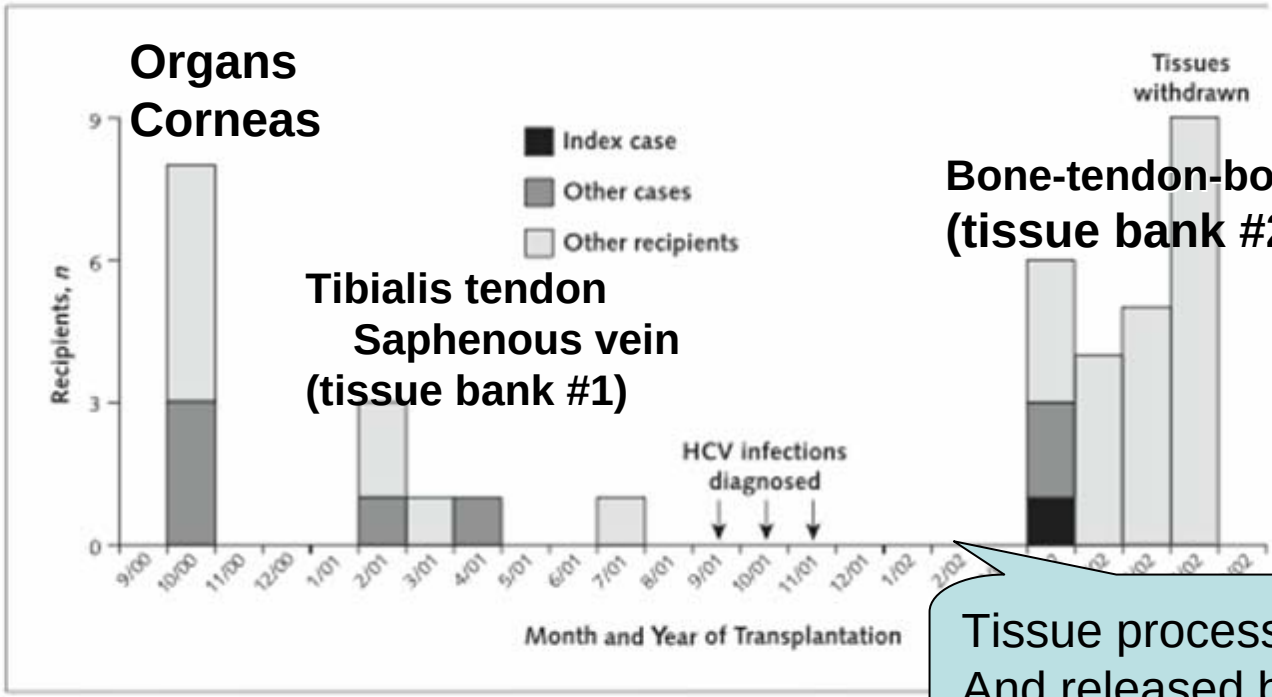
ORGAN RECIPIENTS -- OCT 2000
Lung HCV infection
Liver?
Heart --died early
Kidney HCV Infection
Kidney?

TISSUE RECIPIENTS
Corneas (Italy)---- Oct 2000
Saphenous Vein HCV infection ----2001
Tibialis Tendon HCV Infection---- 2001
Patellar Tendons HCV infection ---2002
Skin
Bone (gamma irradiation)

Annals of Internal Medicine 2005; Vol 143: pages 648-654

Significant Communication Delay

Figure 1. Transplantation of grafts from a donor with hepatitis C virus (*HCV*) infection, by month of transplantation and case status (n = 38), United States, 2000–2002.



Tissue processed
And released by
tissue bank #2

Dates of transplantation for 2 recipients were unknown. Hepatitis C virus infection was diagnosed in … nd November 2001. These recipients had undergone transplantation in February 2001, October 2000, and April

Better recognition of donor as source and better communication could have halted tissue processing, release and infections in 3 more patients.

HCV FROM SERONEG DONOR: 37
37 Recipient follow-up

- **32 TISSUE RECIPIENTS TESTED**
- **3 Previously HCV infected**
- **2 recipients not found (bone, bone-tendon recipient)**
- **FIVE of 27 were HCV RNA POS genotype 1a**
  - **1 (?2) of 2 saphenous vein recipients (reported to CV tissue bank 2001 but bank thought it was not from vein)**
  - **1 of 3 tibialis tendon recipients**
  - **3 of 3 bone-tendon-bone recipients**
- **22 of 27 were NEG (2 skin recipients and 16 irradiated bone recipients)**

MMWR 2003;52:273, Ann Intern Medicine 2005; 143:648-654

Sources of Infections Transmitted by Tissue Allografts from Deceased Donors

- Postmortem endogenous contamination of donor tissue at time of tissue recovery (noninfected donor)
  - Yeast: frozen heart valves
  - Bacteria: fresh cartilage*, frozen tendon*
  - Bacteria, yeast : cornea*

* Reported in 2002, 2003, 2006

Sources of Infections Transmitted by Tissue Allografts from Deceased Donors

- **Unusual bacteria acquired from tissue bank processing environment**
  - **Contaminated HBSS washing reagent: Frozen pericardium**
  - **Environment: Frozen tendon***

……

- **? Bacteria acquired from hospital operating room environment?**
  - **?source: Frozen tendon***

*** Reported in 2002, 2006**

Recent Lack of traceability

- **2002 HCV case**
  - **2 (5.4%) of 37 not identified**
- ***2006 Chryseobacterium meningosepticum* cases**
  - **6 (0.1%) of 48000 recipients not found**
  - **(distributors not used)**
- **2005-6. (preliminary results) BTS tissue recall (New Jersey fraudulent tissue recoveries)**
  - **2000 (7%) of 28,000 not identified**
  - **(distributors used)**

Lack of traceability during BTS recall/lookback

- ~28,000 tissues from 4 tissue banks
- ~2000 (7%) unaccounted for
  - Failure of recordkeeping, traceability distributors and end users
  - ? Deficiency of tissue distributors > end user, hospitals?

SB May 2000

Milestones for publishing standards for hospital Labs and ORs handling tissues

- **Published Standards for hospitals**
  - **1992 Amer Red Cross****
  - **1993 AABB****
  - **1993 AATB****
  - **Jan 1,1994 JCAHO (for labs)****
    - Inspected under blood bank/lab standards
    - Formal standards published in 1996 CAMPLS
  - **July 1, 2005 JCAHO ****

(for hospital, clinical, ORs)

**** for SOPs, ident supplier, storage, traceability, records**

+/- investigate adv outcomes, recalls

Importance of traceability

- When viral, bacterial or fungal infection is discovered in a recipient and the tissue is suspected to be a possible origin the tissue bank should
  - search to see if same microbe is in donor, tissues, processing environment, supplies, reagents, equipment. (Look for possible source of contamination)
  - Re-evaluate donor source to be sure its not from the donor
  - Distribution of similar tissue should stop
  - Test tissue in inventory
  - Withdraw tissue already distributed and test for contamination
  - The other recipients of tissue from same donor processed at same time, same batch need to be investigated for the same type of infection
    - Tissue distributors and Hospitals need good records

Viral infection transmitted from cadaveric donors by tendon transplants (minimally processed)

- **HIV**
  - **1985* From anti-HIV 1.0 Neg Donor** (discovered 1990, NEJM 1992, 326:726)
- **Hepatitis C Virus**
  - **1990* From anti-HCV 1.0 Neg, anti-HCV 2.0 POS Donor** (discovered 1992, JBJS 1995, 77:214)
  - **2000 From anti-HCV 3.0 Neg, HCV RNA Pos Donor** (discovered 2002, MMWR 2003, 52:273)

*In several cases of infected donors, Hospitals have not been able to trace the tissue to all recipients

Not all recipients were able to be found for testing

HIV FROM BONE & TENDON ALLOGRAFTS 1985

- **1985 Donor had no known risk factors. Anti-HIV test NEG (Test was not sensitive in 1985)**
- **Donated multiple organs and tissues**
- **First infected recipient discovered in 1990**
  - HIV Transmitted by
    - 3 freshly transplanted organs
    - unprocessed frozen tendon,
    - two unprocessed frozen femoral heads,
  - Not transmitted by
    - freeze-dried tendon (cells removed from bone ends, antibiotic soaked),
    - freeze-dried bone(cells removed, ETOH soak) or
    - irradiated dura

NEJM 1992;326:726

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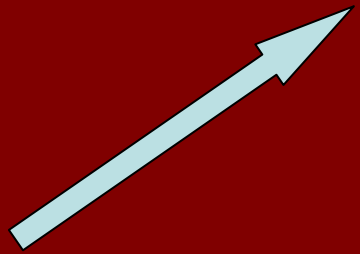
Simonds et al NEJM 1992;326:726

HCV transmitted by frozen bone & tendons Conrad, Strong et al JBJS 1995; 77-A:214

- **Cadaveric donation in 1990, anti-HCV 1.0 Neg**
- **When anti-HCV 2.0 test available, inventory tested**
- **Two cadaveric sera, retrospectively, found POS with anti-HCV 2.0.** Search for previous patients who received tissue from these donors
  - Transmitted by frozen, unprocessed tendon & bone
  - Not transmitted by freeze-dried irradiated bone
- Some recipients not notified, found, tested
  - Physicians decided not to notify some bone,tendon recipients
  - Some hospitals had poor records and could not identify skin recipients

HCV Transmission by Organ & Tissue Allografts From a Seronegative Donor (HCV RNA Positive)

Cadaveric Organ & Tissue Donor



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Kidney HCV Infection
Kidney?

TISSUE RECIPIENTS

Corneas (Italy)
Skin
Tendon HCV infection
Saphenous Vein HCV infection
Bone (gamma irradiation)

HCV FROM SERONEG DONOR: Recipient follow-up

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MMWR 2003;52:273

HCV FROM SERONEG DONOR: Recipient follow-up

- **Donation 2000 Organs: corneas, skin transplanted**
- **Tendon, bone stored frozen until processed in Mar 2002**
- **Two patients who received tendons infected 2002, investigation begun**
- **Unable to identify one recipient of tissue**
- **All recipients found and evaluated, except one recipient .**

Matt Kuehnert MD, CDC (As of Oct 18, 2005)

Current Status, Most Hospitals

- Location: OR
- Staff
  - One RN coordinates
  - OR mgr "supervisor, responsible head"—in perioperative, surgical services
- Written standard operating procedures
  - In existence only since 2005 due to JCAHO/TJC standards
  - Incomplete
- Incoming inspection
  - Transport conditions OK
  - Packaging integrity, tissue ID
  - Log in (electronic and paper)*
- Record of inventory in freezer/ room temp
  - Electronic and paper*
- Store: freezer, room temp
  - Monitor freezer, alarms
  - No monitor of room temp
  - Occasionally some allograft stored on consignment @ RT
- Release tissue from storage
  - Inspection of tissue
  - Log out*
  - Record of final use* (patient and MD, date) or discard or waste
- prepare in OR
  - Thaw
  - Reconstitute freeze-dried tissue
- Record in patient's medical record after implant*
  - Type of allograft and unique ID*
  - Complete tissue use form and return to tissue bank manufacturer (not necessarily to the supplier/distributor)

*critical elements for traceability

Traceability

Organizational efforts to improve started in early 1990s

Milestones in tissue transmitted infections and standards for hospital Labs and ORs

- **Published cases disease transmission :**
  - **1992 HIV (1985, discovered 1990)***
  - **1995 HCV (1990, disc 1992)***
  - **2002 HCV (2000, disc 2002)***
  - **2002-2006 Bacteria***

  ***showed poor traceability of recipients**

- **Published Standards for hospitals, dentists**
  - **1992 Amer Red Cross****
  - **1993 AABB****
  - **1993 AATB****
  - **Jan 1,1994 JCAHO (labs)****
    - Inspected under blood bank standards
    - Formal standards in 1996 CAMPLS
  - **July 1, 2005 JCAHO ****

(hospital, clinical, ORs)

** for SOPs, ident supplier, storage, traceability, records

+/- investigate adv outcomes, recalls

Ted Eastlund
President,
(1992-1993)
American Association of
Tissue Banks

Jeanne Mowe
*Executive Director, American
Association of Tissue Banks

MEETNG was with JCAHO's :

**Van Ostenberg, Anne Belanger,
Curt Niederee, MD, Marilyn Sims**

July 8,1993

**AATB Visited JCAHO
in Chicago**

Showed them AABB & ARC standards for hospitals and the blood bank model

To propose new hospital standards for handling tissues:

**SOPs, traceability, records, storage, investigating adverse outcomes, recalls etc
(proposal accepted)**

TJC (JCAHO) Tissue Requirements:

1994-2004.

In JCAHO laboratory standards

(but tissues in OR, not lab, blood bank)

Fall 2004

Technical committee proposed to move standards to hospital clinical section with revisions

Effective 7-1-05

Tissue handling in hospital (and OR) standards, not just in lab standards

Problems found in hospitals 1994-95

- Tissues Handled mostly in OR, occasionally in blood banks, rarely in pharmacies
- Problems Found?
  - In labs/BB: “none to rare” (1 case)
  - In ORs: serious problems in over 50% of ORs
- Poor recordkeeping (traceability)
  - No tracking mechanism at all in some ORs
  - Partial tracking in others
- Improper tissue storage temperature monitoring in many ORs
  - No temp monitored on weekends
  - Lack of alarms on freezers
  - No temps monitored ever
  - Alarms not checked for response
  - For freeze-dried tissue (room temp), no knowledge of limits of RT acceptability

(no improvement from my surveys in late 1980s)

Current Problems Regarding Handling

--Lack of reliable & complete traceability

- Several hospital ORs resort to billing records as only method available
- (at least as seen in hospitals pre-1995 TJC standards)

HTS

Structural Issues

HTS
Hospital Tissue Service

The hospital entity
that
acquires, stores and provides
an
adequate ,safe and effective
supply
of
tissue autografts and allografts
(bone, tendon, cartilage, heart valves, vessels, skin etc)
and
ensures
cost-effective and clinically appropriate use.

Main components of transfusion/tissue “system”

TISSUE AND BLOOD SUPPLIERS

TISSUE DISTRIBUTORS

“END USERS”, HOSPITALS, SURGICENTER, DENTISTS

Main components of transfusion/tissue "system"

TISSUE AND BLOOD SUPPLIERS

(blood centers, tissue banks)

- **Gain public support for donation**
- **Identify and recruit donors**
- **Donor eligibility determination (med Hx, Soc Hx, exam, testing)**
- **Blood collection, tissue recovery**
- **Processing**
  - **Including disinfection, sterilization**
- **Storage**
- **Distribution to hospitals**
- **Investigate reports of adverse outcomes, initiate lookbacks, recalls**

TISSUE DISTRIBUTOR

- **Buy from tissue bank**
- **Store**
- **Sell to hospital**

Main components of hospital transfusion/tissue "system"

"END USERS" HOSPITALS, (SURGICENTERS, DENTIST OFFICE ?)

Qualify tissue/blood supplier (vendor qualification: meets requirements)
Incoming inspection, log in
Recordkeeping (traceability)
Storage, monitored
Selection of correct tissue/blood
Tissue preparation in OR/blood administration

……

A responsibility to assure availability of safe, effective tissue/blood

……

Investigate and report adverse outcomes
Respond to recall, lookback investigations
Peer review of appropriate use of tissue/blood
    ----Monitor appropriate clinical use
Medical staff overview (Transfusion committee)
    ----appropriateness, availability, errors, safety, near misses, etc
Medical director function (evaluate adverse outcomes, monitor appropriateness of use, approve procedures and deviations from procedures, consultations)

……

Based on the elements of a hospital blood transfusion service

C. SORDELLI INFECTION - INVESTIGATION

- Tissue Processed After Body Stored at Room Temperature for 19 Hr (Plus 4 Hr Refrigerated) . Room Temp Storage Time Beyond AATB Standards. The tissue bank is not AATB-accredited
- 19 Unused Tissue From Same Donor were cultured
  - 2 Grew *C. sordelli* (Fresh Fem. Condyle, Frozen Meniscus)
  - Processing Fluid Bathing Allografts Grew *C. sordelli*
- Tissue Bank Processing of distal femoral condyles, meniscus
  - No Preprocessing Cultures (other tissue banks do cultures at procurement)
  - Aseptic Processing. No Disinfectant. No Sterilization step
  - Antibiotic Soak was used.
  - Final Sterility Test: Companion Tissue (Cartilage) Cultured After Antibiotic Exposure - No Growth.
  - No Other Final Sterility Tests (Actual femur condyle and meniscus not cultured.)

MMWR 2002;51(Mar 15):207-10.

Special expertise a hospital blood bank offers to serve as a hospital tissue service

- Experience in meeting federal regulatory and professional standards requirements
- Experience in investigating and reporting adverse outcomes
- Experience in notifying suppliers and the FDA of serious adverse outcomes
- Experience in managing recalls and lookback investigations
- Medical director to overview operations, to ensure investigation of adverse outcomes, to overview appropriate use of materials, to liaison with practicing physicians who use the materials, and to ensure that the needs of using physicians are met
- Experience organizing medical staff overview in the form of a Transfusion committee.

All these activities are appropriate to apply to handling human tissue allografts

Current Status

END USERS: Hospitals, surgicenters, dentist offices, clinics

--- Acquire, inspect, log in, store, record, release and prepare, provide to OR, surgeon

GOOD PERFORMANCE

- **Good storage, improved traceability and recordkeeping**
- **Meeting requirements of surgeons well**
- **Quality programs in hospitals**
- **Meeting JCAHO requirements in improved fashion**

- **----------**

VARIABLE, DEFECTIVE, ABSENT PERFORMANCE

- **Vendor qualification?**
- **Medical director availability**
- **Investigation of adverse outcome**
- **Lookback investigations**
- **Recalls**
- **Centralized authority, responsibility**
- **Peer review of appropriate use of tissues**

Hospital (HTS) Investigation of Infection

- Investigation at the hospital level needs to:
  - Evaluate whether the infection arose from the patient
  - Evaluate whether the infection arose from the hospital environment
- Report to supplier, ?FDA

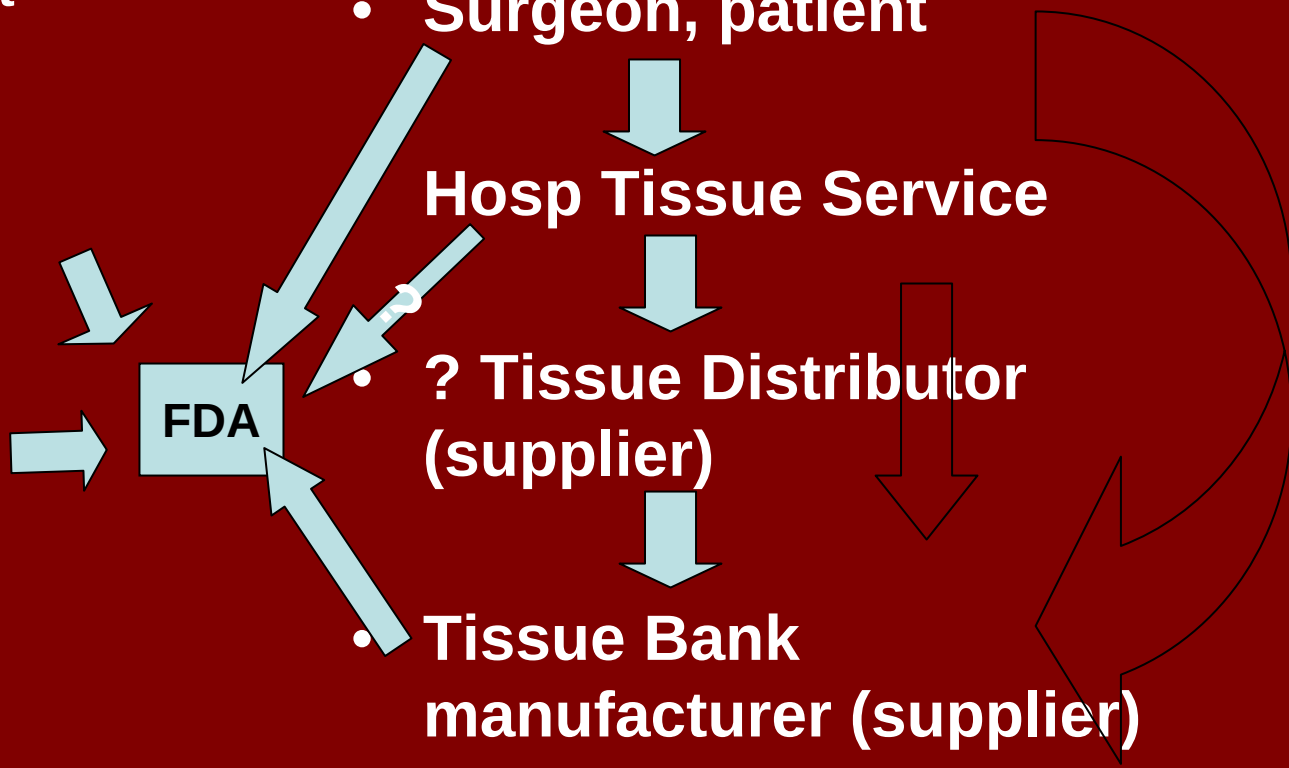
Reporting allograft associated infection

TRANSFUSION

- Physician, Patient
- Blood bank, BTS
- Blood supplier

TISSUE USE

- Surgeon, patient
- Hosp Tissue Service
- ? Tissue Distributor (supplier)
- Tissue Bank manufacturer (supplier)



Transplanting Surgeon's Responsibilities

HTS should periodically educate surgeons of their responsibilities to report to the HTS:

1. Recently diagnosed infections:
   - HIV, hepatitis within 6 mo of any tissue graft
   - WNV within 4 weeks of fresh, viable graft
     - Cartilage, skin, cornea, heart valves
   - CJD, vCJD within 3 decades of dura, cornea, nerve graft
   - Fungal infection that is multifocal, systemic eg, embolic causing stroke, blindness, osteomyelitis within 3 years of heart valve, vein graft
   - Deep bacterial graft site infection that is unusual and suspected to be caused by graft
2. Graft failure that is unexpected or unusual and suspected to be due to defective allograft

AABB Tissue Committee

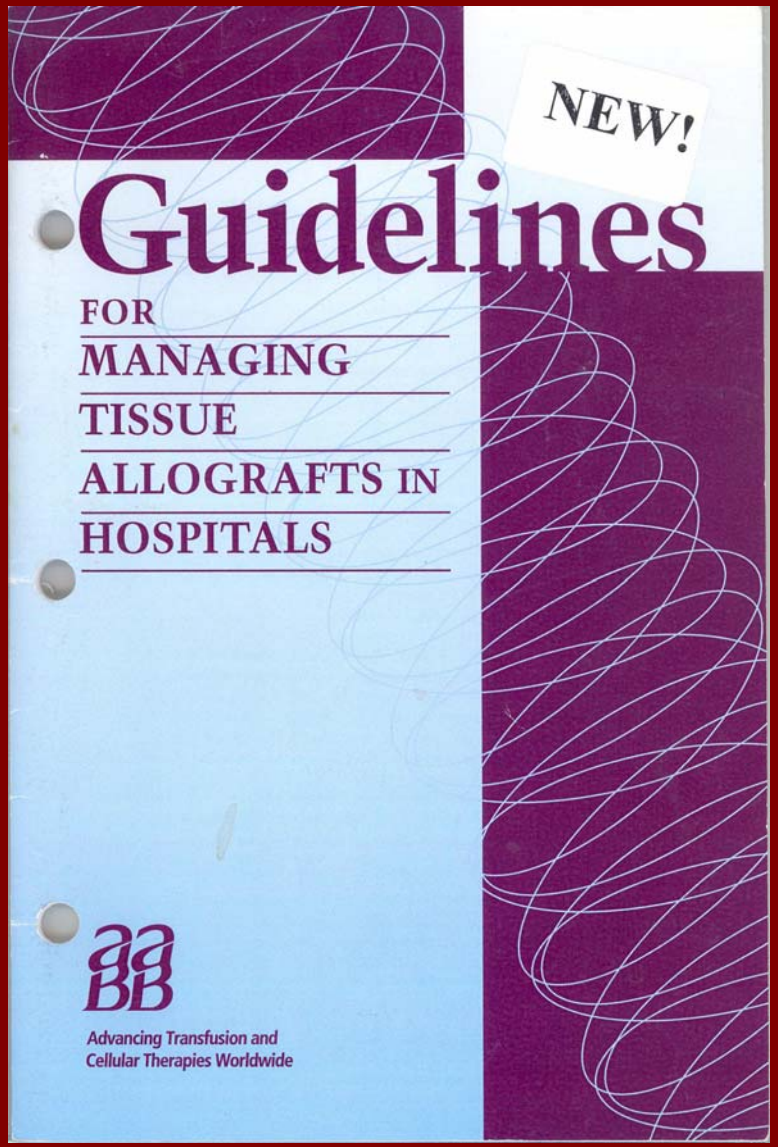
(includes reps from TJC, FDA, EBAA, AATB, armed forces, AAOS, CDC)

- AABB survey of hospitals, where are tissues handled?
- Guidelines for hospitals handling tissues (Oct 2006)
- Future Handbook for Hospitals Handling Tissues
- Audioconferences
- Update standards for hospitals handling tissues
- Educational programs (annual mtgs)

2005 AABB Survey of Hospitals

- Human tissue oversight in hospitals: an AABB survey. Kuehnert M et al TRANSFUSION 2007;47:1537

- 402 OF 940 ACCREDITED HOSPITAL BLOOD BANKS RETURNED SURVEY
  - In 76% of hospitals, tissues entirely handled by ORs
  - In 51% of hospitals, hospital blood banks had some role, e.g, varying from providing frozen storage to full control



Content

Oversight Responsibility for Tissue Management

Obtaining Tissue Grafts: Supplier Qualification .

Inspection and Documentation Upon Receipt. .

Process Control and Tissue Allografts . .

Traceability and Record-Keeping

Storage of Transplantable Tissue

Investigating and Reporting Adverse Events

Handling Tissue Recalls and Withdrawals

Published by AABB October 2006 -------- 20 pages
a guide for compliance with TJC(JCAHO), AABB, AATB, EBAA standards

AABB Standards and required blood bank physician overview

(Should equal requirements be made for a hospital tissue service?)

APPROVAL OF BLOOD BANK PROCEDURES

APPROVAL OF DEVIATIONS FROM Procedures

RELEASE OF BLOOD COMPONENTS (if specifications not met)

DEVELOPING BLOOD ADMINISTRATION PROCEDURES?

DEVELOPING RECIPIENT CONSENT PROCEDURES

DETERMINING INDICATIONS FOR USE OF BLOOD COMPONENTS

EVALUATING ADVERSE OUTCOMES OF TRANSFUSION,

Hospital Tissue Services medical director responsibilities (proposed)

- Review, approve and sign medical-technical procedures
  - Approve deviations from written procedures.
- Conduct investigations of infectious complications and other adverse outcomes of tissue allograft transplants
- Ensure lookback investigations are performed, physicians notified & recipients tested
- Ensure recalls are performed when due to tissue safety or effectiveness issues
- Assist in evaluating suitability of autologous tissue obtained from other hospitals
- Assist in evaluating qualifications of tissue suppliers, as needed
- Ensure that FDA, HRSA and JCAHO/TJC requirements and AATB, AORN, UNOS and AABB professional standards are met
- Participate in peer review of appropriateness of tissue allograft use

Proposed guidelines: Hospital Tissue Transplantation Overview Committee

- Review HTS practices
  - to ensure that tissue allograft supply is safe, adequate, effective and of high quality
  - activities including usage trends, outdating, wastage, supply shortages
- Review adverse outcomes of tissue allograft use
- In consultation with the medical staff, establish guidelines for the use of tissue allografts.
  - Establish criteria and guidelines for auditing use of tissue allografts, reviewing those not meeting audit criteria and reporting those not justified by existing Guidelines to the Clinical Service involved.
- Review HTS regulatory and accreditation inspection reports.
- Review HTS QA reports and participate in QI efforts,
  - including review of deviations, errors and near misses requiring corrective and preventive action

SUMMARY

- The risk of infectious disease transmission from tissue allograft transplants is low and mainly with fresh or minimally processed allografts
- Hospital handling of allografts needs improvement, particularly regarding tissue tracing, investigating adverse outcomes and identifying and centralizing responsibilities
- All the basic elements of a transfusion service need to be implemented in the HTS
  - Hospital blood banks are currently best suited for handling tissue in hospitals
- Implementing existing AATB, AABB and JCAHO requirements will make transplants safer by being able to trace recipients when needed and by improved investigating reports of infections.

Questions to speakers

- **Current state of safety? (tissue allografts)**
  - **Risk very low and mainly associated with unprocessed fresh and frozen allografts: tendon, cartilage, corneas**
  - **(not with tissue sterilized or freeze-dried)**

- **Commonality with transfusion, organ & tissue transplantation safety?**
  - **Human origin: donor-to-recipient disease transmission risks**
  - **Adverse outcomes need investigation and reporting and preventive actions**
  - **Handling of tissue in hospitals should be like handling blood**

Suggestions to improve safety

Hospital Tissue Services level

Require all elements of a transfusion service to be part of the hospital tissue service, particularly:

Recordkeeping, traceability
Thorough investigation and reporting of adverse outcomes*
Ability to perform lookback investigations*
Medical director overview*
Medical staff committee overview*

……

All these elements must be present regardless of site (OR v BB) but for many hospitals it makes sense to move responsibility for tissues from OR into blood bank

……

***Increase medical director role in hospital tissue services**

……

Develop a system for recognizing and managing tissue-related infections

Most important resources are needed in the following:

- **Improved identification at surgeon and hospital level**
- **Improved hospital investigations**
  - **Exclude hospital environmental and patient sources before concluding that the allograft was the source**
- **Reporting, trending and tracking at a national level**

? Any questions?