Blood and Tissue Safety from an Orthopaedic Surgeon's Perspective

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Invited Presentation: Advisory Committee
On Blood Safety and Availability

Is there commonality among blood and organ and tissue transplantation?

Perspective

multifaceted

- AAOS member, Biological Committee member
- AAOS tissue safety educational handout 2007, Scientific Exhibit
- Orthopaedic Surgeon, Cleveland Clinic
- Past Tissue Banker Cleveland Clinic, CWRU
- Past President AATB 1997-99, currently Standards committee member, Lifetime Service Award
- AABB Tissue Advisory Committee member (AAOS rep)

  ("Guidelines for Managing Tissue Allografts in Hospitals"), new handbook- more detail- being published
- Transplant Transmission Sentinel Network (TTSN) Task Force

  Co- Chair (tissue side)
- Medical Director Musculoskeletal Tissue Bank CCF
- Recipient demineralized bone powder

What is the overall message "we" would like to provide to the Public

- Musculoskeletal Allografts are safe and the use of these allografts provide the opportunity for improved function and enhancement concerning quality of life.
- Transmission of disease is a very rare event with over one million allografts being used on a yearly basis.
- Strides have been made to have allografts become even safer through further FDA Regulations and Guidelines and AATB Standards and Joint Commission Standards for Tissues
- Blemishes over the past years have been associated much more so with non-accredited AATB situations in recovery and processing
- AAOS Advisory Statement: Comments

AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

Advisory Statement

Use of Musculoskeletal Tissue Allografts Dec 2006

The American Academy of Orthopaedic Surgeons (AAOS) believes that for appropriate patients musculoskeletal allografts represent a therapeutic alternative. These tissues should be acquired from facilities that demonstrate compliance, use well-accepted banking methodology and follow Food and Drug Administration (FDA) Good Tissue Practices. The AAOS urges all tissue banks to follow rigorous national guidelines and standards1,2 and recommends the use of tissue from banks that are accredited by the American Association of Tissue Banks (AATB).

Musculoskeletal allografts, including bone, cartilage, tendons and ligaments, are being used to address the reconstructive needs of a growing number of patients each year. As such, these scarce human resources are part of larger national programs involving a variety of transplantable organs and tissues. While the incidence of disease transference with allografts is very low, careful donor screening and tissue processing are crucial in order to minimize potential risk to the recipient. Collaboration by the orthopaedic community with a broad range of scientific, tissue bank, regulatory organizations, and clinical interest groups can help ensure that the musculoskeletal allografts available for human transplantation can be used safely.

The AAOS strongly favors on-site inspection and accreditation of tissue banks that demonstrate compliance with appropriate standards. All tissue recovery partners of AATB accredited banks are also subject to the same standards, as required by FDA regulations.2

Guidelines and standards for the acquisition, processing, and banking of musculoskeletal tissues for human transplantation have been developed. 1,2 The guidelines are based on current scientific information and the consensus of a broad representation of knowledgeable professionals from the government, academia, medical professionals, and industry. Having been subjected to repeated scrutiny and frequent revisions, these guidelines have become widely accepted and utilized

The comprehensive allograft tissue guidelines and standards address donor selection and screening, tissue recovery techniques, graft processing methodology, storage approaches, and record keeping. The use of such guidelines and standards best protect patients receiving these allografts and, thereby, best serve the interests of patients and orthopaedic surgeons. It is particularly important that donors be screened utilizing past medical history, serologic and bacteriologic tests and, when available, autopsy findings to mitigate the potential for disease transference.

The AAOS supports informed consent, for both the donor family and the recipient of human tissue, in accordance with local, state and federal regulations and laws.

The AAOS encourages orthopaedic surgeons to cooperate with efforts by local, regional and national organizations to educate the public and health care professionals concerning the need for tissue and organ donation in support of both clinical transplantation and research, and to participate in the implementation of these important efforts. The AAOS additionally encourages the establishment of a national network to maximize the availability, equitable distribution and utilization of these scarce transplantable musculoskeletal tissues. Such a network should also serve as a means to acquire data and information reflecting the ongoing clinical experience with musculoskeletal allografts, while providing a vehicle for public and professional education.

In fulfilling the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)3 requirements for hospitals, the orthopaedic surgeon should when possible, facilitate the tracking of the allograft with the tissue recipient. This includes participation in standardized processes for tissue handling in the hospital, facilitating record keeping for traceability, participating in the investigation of recalls or adverse events as related to an implanted allograft, and reporting adverse patient outcomes to the hospital, tissue bank, and the FDA's adverse event reporting system, Medwatch (*file:///C:/Documents%20and%20Settings/sale/Local%20Settings/Temporary%20Internet%20Files/OLK19/attachment_44_standards_changes.pdf*).

"Standards for Tissue Banking," American Association of Tissue Banks, 1320 Old Chain Bridge Rd., Suite #450, McLean, VA 22101, (703) 827-9582. http://www.aatb.org/

FDA, 21 CFR Part 1271. Human Cells, Tissues and Cellular and Tissue Based Products: Registration and Listing, Donor Eligibility Requirements and Recommendations, and Current Good Tissue Practices. Final Rule May 25, 2005 http://www.fda.gov/cber/tissue/docs.htm.

Joint Commission on Accreditation of Healthcare Organization (JCAHO) requirements Applicable to Hospitals PC 17.10, PC.17.20, and PC 17.30. http://www.jcrinc.com/subscribers/perspectives.asp?durki=9159&site=10&return=6061


MUSCULOSKELETAL ALLOGRAFT TISSUE SAFETY
AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
COMMITTEE ON PATIENT SAFETY
COMMITTEE ON BIOLOGICAL IMPLANTS
TISSUE WORK GROUP


SE614 Safety of Musculoskeletal Allograft Tissue
AAOS Committee on Patient Safety/Tissue Work Group
TISSUE TRANSPLANTATION SAFETY IN ORTHOPAEDIC SURGERY
Committee on Patient Safety
Committee on Biological Implants
Tissue Work Group
BASIC AWARENESS
What are the Milestones in Tissue Banking?
What has Occurred in Government Regulation?
What Practical Steps are Taken in Tissue Banking in Assessment and Processing?
What are the Episodes of Documented Disease Transmission?
What is its Message?

MUSCULOSKELETAL ALLOGRAFT TISSUE SAFETY

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
74th Annual Meeting
February 14 - 18, 2007
San Diego, California

COMMITTEE ON PATIENT SAFETY
COMMITTEE ON BIOLOGICAL IMPLANTS
TISSUE WORK GROUP

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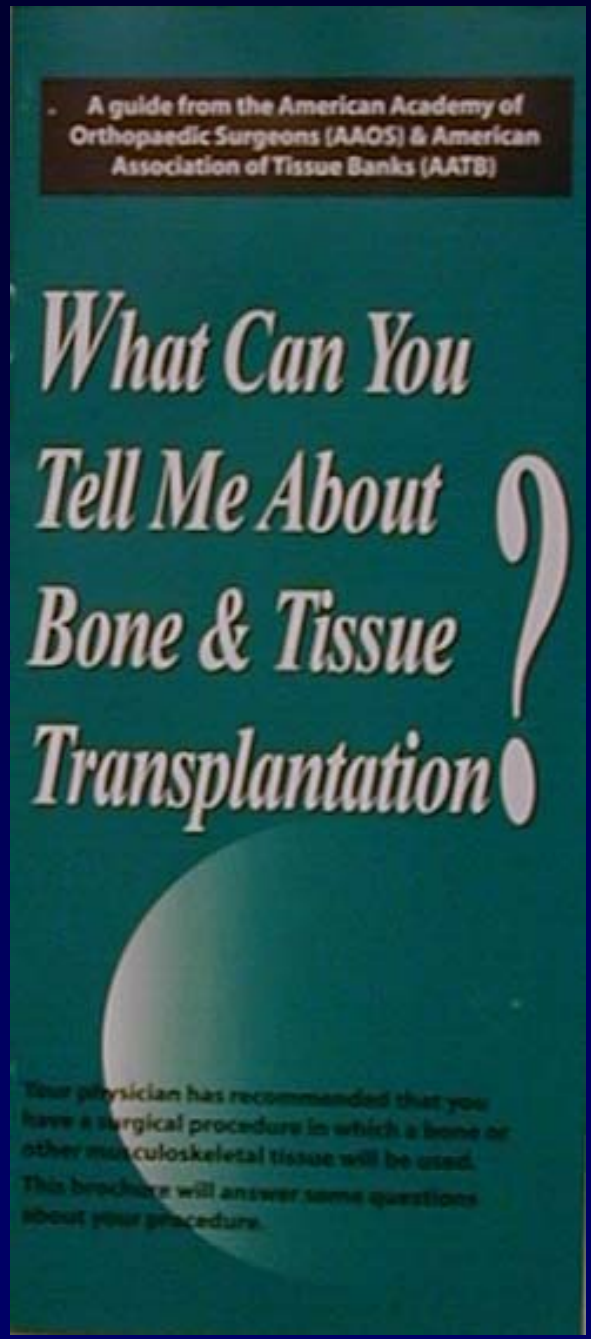
MUSCULOSKELETAL TISSUE

Guide from AAOS

and

AATB



Recent FDA Milestones

- Registration
- Donor Eligibility
- Validation of Processes by tissue banks and processors

All culminating in

Current Good Tissue Practice for HCT/Ps

May 2004 with final implimented by May 2005

Guidelines: Donor Eligibility

- Published February 27, 2007…parameters must be instituted ASAP but by Aug 28, 2007
- Confusion for an orthopaedic surgeon when “non-binding” on each page of document
- Mandated (not just “guideline recommendation”) for NAT HIV and HCV for donors recovered after Aug 28, 2007 …reduces window time period (antibody issue) for a positive test)
- AATB requirement for NAT since March 9, 2005
- What about inventory….2-5 yrs?

  Not addressed

Joint Commission

Joint Commission on Accreditation of Healthcare Organization (JCAHO) requirements Applicable to Hospitals PC 17.10, PC.17.20, and PC 17.30.

July 2005

- This mandates hospitals, outpatient surgical centers, and facilities that are JC accredited to participate in tissue traceability.
- That means the recipient cards that have minimal information: tissue ID, hospital facility, surgeon, date, limited recipient info (hosp #)…sent back to tissue bank
- Just how often is that accomplished- 60-70%
- Tissue Handling in hospital…AABB, JC instructions

Problems of a Master Strategy

NAT HIV and NAT HCV

- Blood by an IND 1999, 2002 FDA licensed test
- Tissue cadaveric test general use 2004, AATB mandated for recoveries after March 9, 2005
- Organs voluntary NAT serology, timeliness of results, OPO decision
- Problems screening v. diagnostic tests, blood from living donor v. cadaveric serum
- Discordant results …late discovery after organs transplanted…when tissue bank runs second sample or even the “first” NAT test

Problems of a Master Strategy

NAT HIV and NAT HCV
West Nile Serology

- Blood….much used, much donated

Organs		Tissue	
Life saving	vs	Life enhancing	(exception Ped Heart Valve)
Short supply		Seldom short supply	

Guidelines: Donor Eligibility

What are we doing with recreational drug non-IV crack and cocaine use?

- Dr. Gocke (MTF) published article identifying ~10% positive serology rate on screened donors that were recovered that had to be discarded after positive serology found after recovery.
- A number of Tissue Banks have taken this published data as a concern and subsequently decline recreational non-IV cocaine and crack donors when found in social history.

Guidelines: Donor Eligibility

- Who makes all the gray zone decisions on donor eligibility?…..person with appropriate training….this need not be a physician (MD, DO)
- AATB requires this to be a physician.
- No one describes what really is appropriate training for this individual making these decisions.
- We have Certified Tissue Bank Technicians…a program established by AATB.
- Is there no way to qualify (certify?) these folks who make these major gray zone decisions? Continuing education issues?

How safe is the tissue I am using?

- Confusion for Ortho Surgeon: As safe as unit of blood?
- Study of ~ 10,000 recovered donors that passed medical hx, physical exam, and social hx screen before money spent on recovery…..~10X more than blood donor discard because of positive serology.
- Tissue donor more at-risk population than blood pool. Zou et al, NEJM 351 (2004) 751
  Stramer et al, NEJM 351 (2004) 760
- Blood donor pool is a repeat donor pool.

How safe is the tissue I am using?

- Depends on processing and the tissue bank

1) “washed” semi processed soft tissue and large bone segments
2) aseptically recovered and aseptically processed grafts (some treated upfront because of pre-processing bioburden with 12-18 kilogray) but never terminally sterilized
3) processed and irradiated grafts (? outcome studies done or just comparison strength studies before implantation)
4) processed and chemically treated grafts (? outcome studies done or just comparison strength studies before implantation)
5) High dose 50 kilogray radioprotectant processed grafts (H_2S odor)

How safe is the tissue I am using?

Labeling Claims- what does “sterile” mean

- Is this 10^{-3}…..one in a thousand….
- Is this 10^{-6}…..one in a million…..

- Some package labeling confusing as to sterility….aseptic processor…validated technique….example label….to the uninformed does this not suggest sterility?

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STORE BETWEEN -40 C AND -80 C

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Graft ID: 06-4026-005
Description:
BISECTED PATELLAR LIGAMENT(FR)
Size:
I=1.5 TL=5.4 BB=12.6 CM
Exp. Date: OCT 11 2011

Processed with Bacitracin / Polymyxin B Sulfate or Gentamicin

R STERILE

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MTF Musculoskeletal Transplant Foundation

Human Allograft Tissue

LBL081 Rev. 07/05

DESCR: ILIAC CREST WEDGE 10-12mm (ACF)

PROD CODE: 100402

DIMEN: T:11mm L:1.8cm W:15mm W2:11mm

SERIAL #: MTF 005592290035 EXP. DATE: 07Jan2010

FREEZE-DRIED Store at Room Temperature. Do not freeze.

Aseptically processed, passes USP <71> for Sterility

Tissue is recovered under aseptic conditions and is aseptically processed. Trace amounts of processing agents may remain. See package insert for these, as well as for contraindications, warnings and preparation for use. FOR SINGLE PATIENT USE ONLY.

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EDISON, NJ 08837
(800) 433-6576

Processed by OSTEOTECH INC. Innovators in Musculoskeletal Science

MTF Musculoskeletal Transplant Foundation

Human Allograft Tissue

LBL081 Rev. 07/05

GRAFTON(R):10cc GEL
Demineralized Bone Matrix (DBM)
PROD CODE: 121150
LOT #: MTF 006517610097 EXP. DATE: 06Jul2009
Store at Room Temperature. Do not freeze.

Aseptically processed, passes USP Sterility Tests

Tissue is recovered under aseptic conditions and is aseptically processed. Trace amounts of processing agents may remain. See package insert for these, as well as for contraindications, warnings and preparation for use. FOR SINGLE PATIENT USE ONLY.

125 May Street
Edison, NJ 08837
(800) 433-6576

Processed by OSTEOTECH INC Innovators in Musculoskeletal Science

MTF Musculoskeletal Transplant Foundation

Human Allograft Tissue. Passes USP<71>For Sterility

DESCR: Fem Cort Strut, Left Med (Thirds)

PRODUCT CODE: 450970

DIMEN: **L:25.8cm T:23.5mm W:3.6mm**

SERIAL#: 041509251014 EXP. DATE: 21Sep2010

FROZEN: Store at -40 degrees C. to -90 degrees C.

Tissue is recovered under aseptic conditions. Tissue is aseptically processed and passes USP<71>for sterility. Trace amounts of processing agents may remain. See package insert for these, as well as for contraindications, warnings and preparation for use. FOR SINGLE PATIENT USE ONLY.

125 MAY STREET
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(800) 433-6576

041509251014450970

MTF Musculoskeletal Transplant Foundation

Human Allograft Tissue

LBL081 Rev. 07/05

DESCR: FASCIA LATA (Large)

PROD CODE: 130140

DIMEN: L:18.0cm W:100mm

SERIAL #: MTF 056569960014 EXP. DATE: 06Jun2011

FROZEN Store at -40C to -90C.

Aseptically processed, passes USP <71> for Sterility/
Treated with Gamma Irradiation

Tissue is recovered under aseptic conditions and is aseptically processed. Trace amounts of processing agents may remain. See package insert for these, as well as for contraindications, warnings and preparation for use. FOR SINGLE PATIENT USE ONLY.

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MTF Musculoskeletal Transplant Foundation

Human Allograft Tissue. Passes USP<71>For Sterility

DESCR: Tib Prox Right OA Graft-APC

PRODUCT CODE: 460385

DIMEN: **L:28.0cm W:28mm W':83mm D':8mm**

SERIAL#: 044521691002 EXP. DATE: 16Nov2010

Frozen:Store at -40 to -90 C. Processed w/10% DMSO

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ORIENTATION VERIFIED

Digital Image

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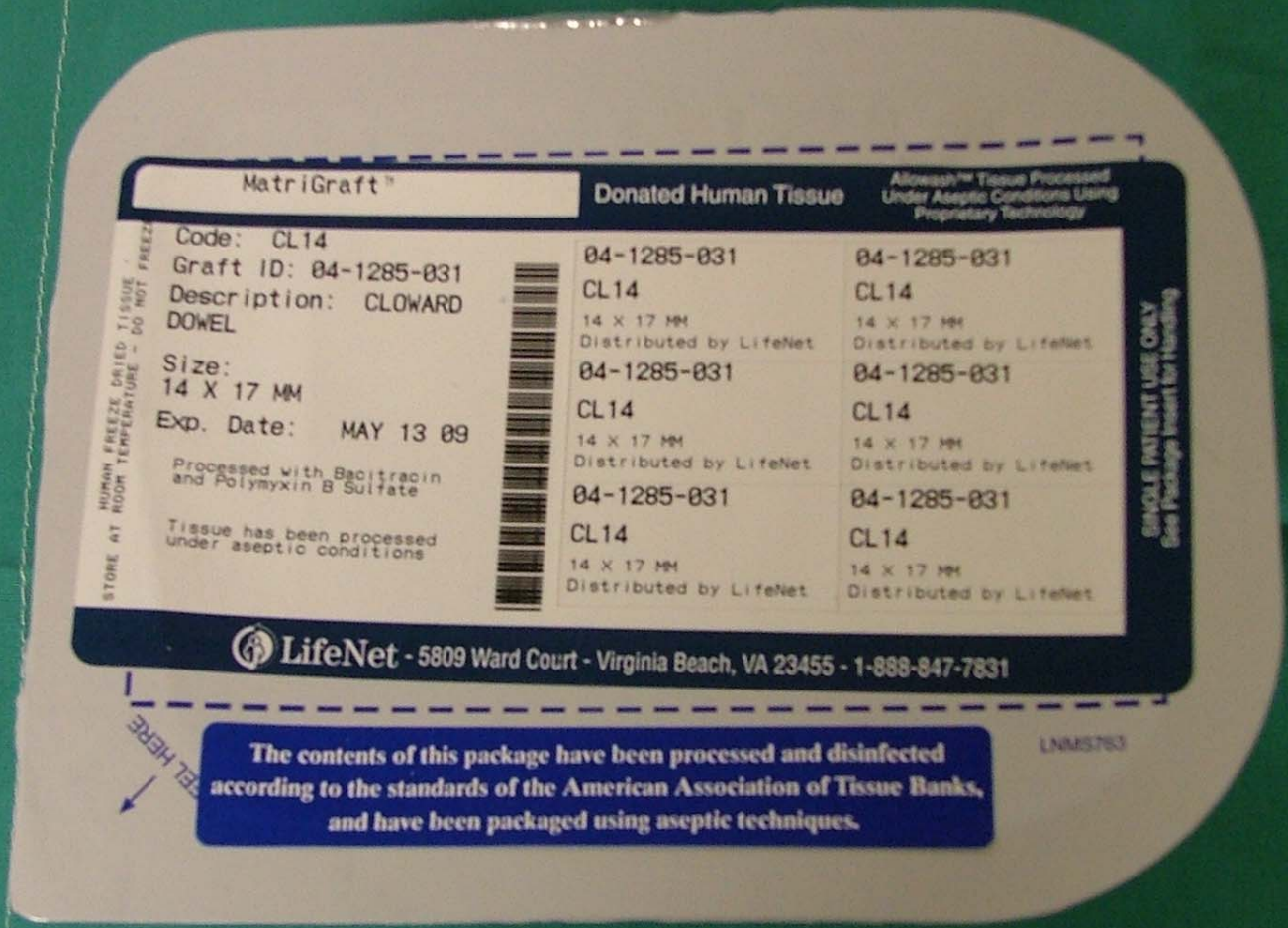
MatriGraft™
Donated Human Tissue
Alloseal™ Tissue Processed Under Aseptic Conditions Using Proprietary Technology
Code: CL14
Graft ID: 04-1285-031
Description: CLOWARD DOWEL
Size: 14 X 17 MM
Exp. Date: MAY 13 09
Processed with Bacitracin and Polymyxin B Sulfate
Tissue has been processed under aseptic conditions
STORE AT ROOM TEMPERATURE - DO NOT FREEZE
HUMAN FREEZE DRIED TISSUE
04-1285-031
CL14
14 X 17 MM
Distributed by LifeNet
SINGLE PATIENT USE ONLY
LifeNet - 5809 Ward Court - Virginia Beach, VA 23455 - 1-888-847-7831
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LNMS783

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Contents: (9) – Blocks
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How safe is the tissue I am using?

- When tissue irradiated 10-18 kilogray…label so states
- Sterility means just bacteria and fungus
- Or does this include viruses….since we know often it takes more than 20 kilogray to deal with high viral bioburdens? ….Sterile for bacteria
- Some companies use chemical validated sterilization that has claims for bacteria, fungus and viruses….but few surgeons aware that this is not used for the demineralized bone products.

How safe is the tissue I am using?

- Some companies using radiation to do terminal sterilization of demineralized bone products (DBMs) without sharing the amount of reduction in osteoinductive properties.
- To date there has never been a substantiated reported case of transfer of disease with DBM products or processed bone chips…
- with HCl and H_2O_2 are we trying to solve a problem that does not exist and decreasing effectiveness in outcomes by irradiating DBM products?

How safe is the tissue I am using?

- Request for a white paper on this topic that accurate statements could made. What is likelihood of disease transmission (bacterial and viral) with various forms of musculoskeletal allografts
- Problem:

  Surgeon bombarded with different tissue processing techniques and different claims…..few address long term in-vivo outcome studies on incorporation/ late laxity or late integrity of the construct (need human outcome studies)

BTS AFTERMATH

- AATB upgraded scrutiny required in yearly audits, donor chart screening when situations of a bank partnering with outside non-accredited recovery source (recovery folks can still lie and falsify data though)
- Track record so far for predominant individual processor concerning technique in “sterilizing” tissue has yielded no confirmed disease transmission
- FDA response to crisis prompt once recognized
- There may easily be other “BTS” entities

BTS AFTERMATH

- User and Hospital Systems elected to focus on donations recovered in funeral homes…as “uncontrolled” settings.

- Most Tissue Banks have excellent parameters for recovery in funeral home settings…and most tissue banks do some funeral home recoveries.
- Although it is possible most of the time for a Health System to stipulate “no tissue from funeral homes”, this is a burden for both the hospital and tissue bank with little derived benefit when tissue is obtained from AATB accredited bank

FEAR

“I am going to culture all my grafts”

- After two hours, back OR instrument table has positive cultures (What are we culturing?)
- Cultures in hospital kept 3-5 days before declared negative
- Tissue Bank cultures kept for a validated 7 or 14 day period of time
- Contaminants
- What does the surgeon do with the results if positive for a couple of colonies?
- Burden to tissue bank for the one colony feedback from hospital…further extensive scrutiny on the donor

FEAR

"I am going to culture all my grafts"

- AAOS needs some help in a unified statement regarding this practice by some done for "medical-legal purposes"

How about an Advisory Statement from Safety Committee?

- We were smart enough to change surgeon behavior about culturing hip and knee joints routinely (when not indicated) for routine TJR procedures….with BTS fear/ published bacterial infections esp. 2002 and recent MTF AP article reported episode…. pressure is to do more rather than just to trust the tissue banker

TTSN PROJECT

- Established after June 2005 CDC/FDA/ HRSA meeting of organ and tissue stakeholders addressing concerns of disease transmission and safety
- UNOS awarded contract 3 year project, into second yr, stakeholder meeting June 2007
- Part A uniform donor number for organs and tissue (linking organs and tissues) with national donor data base through secured web site
- Part B uniform national recipient data base generated at time of organ and tissue use through secured web site…… providing OPOs and Tissue Banks data on respective organ and/ or tissue use (also a real time warning system when tissue recalled or temporarily quarantined before planned use)

TTSN PROJECT

- Part C Adverse Events and “lower level of concern reporting” to national data base.....not to be confused with any elimination of current FDA / CDC systems in place
- This will link organs and tissues when there is a common donor.
- Will allow episodes that are not in themselves alarming (probably never would be reported through MedWatch as single episode) but when cumulative will set off a review and possible immediate (temporary) quarantine

What is the next best serologic test?

What has happened to recipient serology or infectious disease status after organ transplantation?

- Biological marker that has been somewhat ignored
- 1991 HIV published transmission from 1985 organ donor (musculoskeletal tissues)
- 2002 HCV transmission from 2000 Portland organ donor (musculoskeletal tissues)
- Potential cases: Rabies, LCM virus, West Nile virus organ cases

How do we find out about timely organ recipient infections and positive serology changes?

- Need prompt reporting of serology changes and adverse outcome to national data base that links organ and tissue recipients with this common donor….report back to TTSN through the universal common donor number
- Problem: Organ Recipient Transplantation…..no requirement for serology nor prompt reporting in first 3-4 months
- It takes tissue banks 3-4 months from day of recovery to finally release musculoskeletal tissue on the average…can we not build in some requirements to make this work?
- Problem: cost of testing, permission, data collection, communication

Musculoskeletal Allografts Efficacy- do they work?

- DBM with carriers- now devices
- Tissue engineering- more than minimal manipulation…..devices
- Bovine collagen matrix – meniscus….these are not xenografts (FDA) because not living tissue (vCJD)

This is Tissue Transplantation

Musculoskeletal Allografts Efficacy- do they work?

- DBMs…what is amount of osteoinduction?
- Is there an ASTM standard or guideline for measuring osteoinduction? No
- Can the surgeon compare DBMs like comparison of rod strength? No
- Do the bone-tendon-bone allografts stretch out after couple yrs compared to autografts…..what happens to outcomes when irradiated 12-20 kilogray, ? 50 kilogray (Clearant process)
- Nonunions, fx large allografts
- Subacute or late rejection
- Clinician reporting …no data base…outcomes

BLOOD SAFETY ISSUES AT CLINICAL USE LEVEL

- Need for a hospital system wide program for anemic pre-operative patients to lessen transfusion need… thus increasing safety
- Pre-op pt identified as anemic by orthopaedic surgeon or impact internal medicine physician….sort out done so that colon cancer, myeloma, etc not overlooked
- Erythropoietin program initiated that is covered by health care insurance, Medicare, Medicaid, BWC….. if benefit outweighs risk (stroke, DVT issues screened)

BLOOD SAFETY ISSUES AT CLINICAL USE LEVEL

Therefore less blood use

- Less clerical error
- Less infection through unit of blood since less blood use
- Less CHF
- Less immune suppression
- Better Surgical Outcome

BLOOD SAFETY ISSUES AT CLINICAL USE LEVEL

ANTIBODY PROBLEM IN SURGICAL CASES

- Patient comes same day for surgery…sample drawn either day before but not processed or processed the morning of surgery
- Case started promptly…blood eventually needed and request made …told antibody problem…. and it is going to take a couple of hours

HOW DO WE PREVENT THIS SCENARIO?

We solved wrong side surgical procedures….any solutions to creating protocols for this situation?

BLOOD SAFETY ISSUES AT CLINICAL USE LEVEL

QA Issue: How Long Does It Take to Transfuse a Unit of Blood on a Floor Patient Scenario

- Problem: order written, but no current sample in blood bank…
- current glitch…preop outpt sample good for 14 days if no transfusions, however once patient in hospital postoperatively, even if no transfusion in surgery…hospitalization 3 day current blood sample rule invoked….therefore any sample drawn 4 days ago before surgery just became null and void

BLOOD SAFETY ISSUES AT CLINICAL USE LEVEL

- Someone has to recognize on floor (told by blood bank) that sample outdated
- Call made for sample to be drawn (routine blood draw, stat blood draw or resident)
- Blood sample arrives blood bank, crossmatch initiated (routine, stat)
- Phone call to floor eventually to pick up
- IV access necessary

Sometimes a 12 hr period of time passes before transfusion given

BLOOD SAFETY ISSUES AT CLINICAL USE LEVEL

Unnecessary or Over Transfusion Issues

- Does hospital have published transfusion guidelines…. readily shared with staff and residents?
- Who makes decision to transfuse?
- What documentation is needed to be recorded in chart for a patient on floor…. does one need to write why this patient needs a blood transfusion in the notes….does a physician even have to do a hands-on assessment to have a unit of blood given?
- What surveillance system exists to do behavior modification/ education to reduce blood usage and thus improve safety?