
Microsoft®
Health Users Group
TECH FORUM 2008
GOLDEN TICKET
August 26-27, 2008 | Microsoft Corporate Campus | Redmond, WA
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Exceeding Joint Commission patient safety and compliance standards for human tissue transplants with TRACS 4 Life™ and SharePoint

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Agenda

- Biomedical Synergies, Inc.
- Human tissue transplants
- Industry overview
- Regulatory overview
- Joint Commission tissue standards
- Tissue lifecycle in hospitals
- TRACS 4 Life™ overview
- TRACS 4 Life™ demo
- Summary

Biomedical Synergies, Inc. (BSI)

- Founded in Oct. 2005, BSI consults with hospitals regarding compliance with the Joint Commission tissue standards with a focus on patient safety and risk reduction.
- Collectively, the five founding partners of BSI have over a century of health care experience; more than half of which is in the tissue and blood banking industries.

Human Tissue Transplants

- **Bone**: spinal fusion, fracture repair, replacement of diseased bone
- **Skin**: biologic bandage for burn victims
- **Corneas**: sight restoration
- **Ligaments & Tendons**: joint repair
- **Arteries & Veins**: heart bypass, limb salvage
- **Heart Valves**: replacement of faulty valves

Industry Overview

- Transplant of allograft tissue is second most common transplant after blood.
  - In 2007, there were approximately 1.5 million tissue grafts distributed for implantation
  - Allograft tissue products generate $1 billion per year
- Xenografts, bone and other tissues from animals (mostly bovine and porcine), also being used.
  - These require tracking and tracing equivalent to their allograft counterparts.

The Problem

- While working directly in the tissue banking industry, the partners of BSI were witnesses to lapses in quality assurance and improvement, recalls of human tissue products, transmissions of infections due to tissue and resulting deaths.
- We recognized that there were serious issues facing the tissue transplant/implant industry, the hospitals performing the transplants and, ultimately, the patients/recipients.

Diseases Transmitted By Tissue Transplantation

- Bacteria (multiple strains)
- Hepatitis B
- Hepatitis C
- TB
- HIV
- Rabies
- Creutzfeldt-Jakob Disease (CJD)

Case Study

- In 2004, four patients received tissue from a single donor
- Lung transplant died intraoperatively
- The three other organ recipients successful surgeries. All died weeks later of progressive neurological problems
- Laboratory investigations of the three recipients revealed they died of rabies.
- During later investigations it was revealed that the donor had been bitten by a bat.

Case Study

- A fourth patient at the same transplant center who had not received an organ from this donor developed similar symptoms following a liver transplant.
- On autopsy, it was discovered that this patient also died of rabies.
- There was no evidence of cross contamination of this patient and no additional cases of encephalitis consistent with rabies found at the hospital.

Case Study

- During the subsequent investigation, it was discovered that the iliac arteries from the infected donor were not used during the liver transplant.
- They were placed in a sterile container and stored for later use.
- The vessel was used in another liver transplant patient who then died of rabies.
- Because of inadequate labeling, it couldn’t be proven that the vessel absolutely came from the same donor.

HCV from Tissue Transplantation

- Case from 1990 anti-HCV 1.0 Neg donor(retrospectively Pos with anti-HCV 2.0) JBJS 1995; 77-A:214
  - Transmitted by frozen, unprocessed tendon & bone
  - Not transmitted by freeze-dried irradiated bone
  - 21 of 34 recipients not identified

Regulatory Overview

- FDA oversees tissue banks and medical device manufacturers for patient safety
  - Recalls and adverse events tracking
- Joint Commission regulates and surveys hospitals and surgery centers
  - 2005 Tissue standards designed to improve patient safety

Joint Commission Standards for Tissue Storage and Issuance – effective July 2005

PC.17.10

The hospital uses standardized procedures to acquire, receive, store, and issue tissues.

PC.17.20

The hospital's record keeping permits bi-directional traceability of all tissues.

PC.17.30

The organization has a defined process to investigate adverse events to tissue or donor infections

Joint Commission
Examples of Tissues for Inclusion

- Bone
- Cornea
- Skin
- Heart valves/vessels/veins/arteries
- Tendons/ligaments/cartilage
- Bone marrow
- Reproductive tissues (sperm, eggs, etc.)
- Stem cells/cord blood
- Synthetic tissue (artificially prepared, human and non-human based)

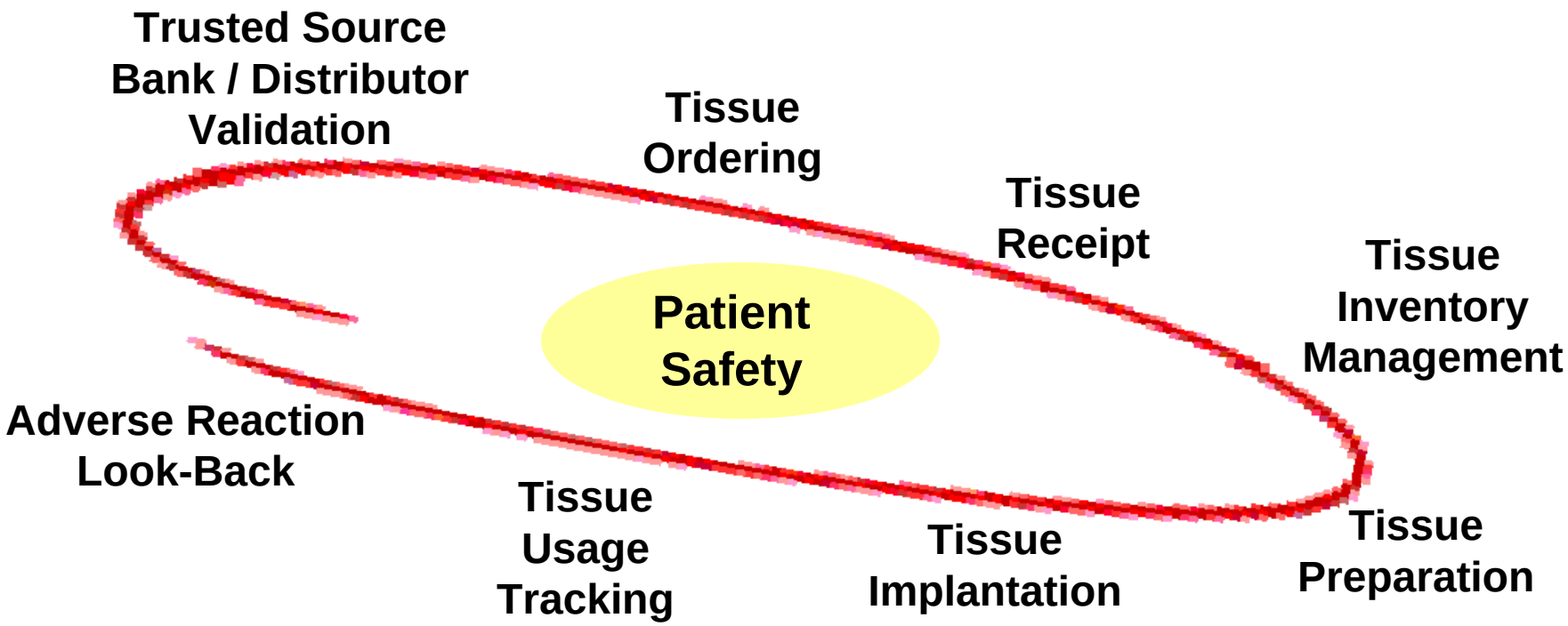
Joint Commission Intervention

- The overall goal of the tissue standards was to enhance patient safety by tracking tissue products to their final dispositions in the event of the worst case scenarios: adverse reactions and recalls.
- As most hospitals in the country struggled to comply with the standards, the tissue industry was about to face its greatest challenge…

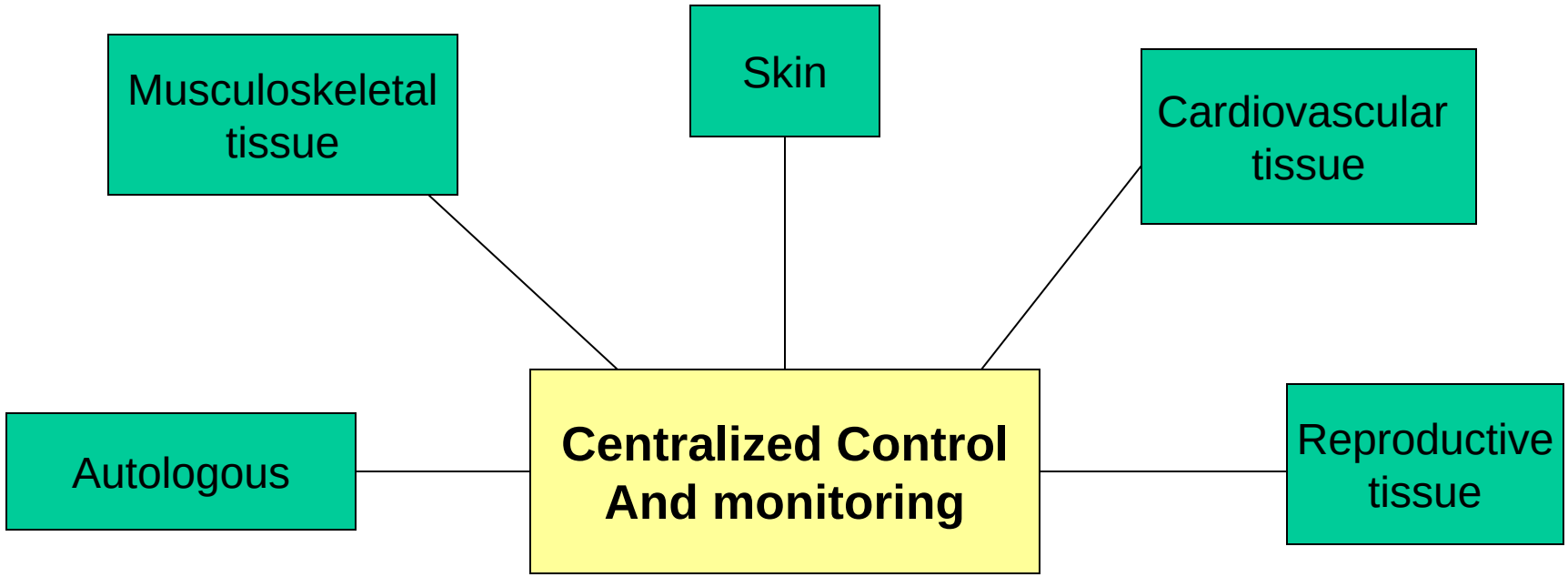
Biomedical Tissue Services Scandal

- In Oct. 2005, the FDA closed down Biomedical Tissue Services for recovering tissue that did not meet FDA eligibility or screening requirements.
- Five major tissue processors/distributors were involved in the nationwide recall of over 20,000 pieces of tissue that ensued – the largest recall in industry history
- This scandal demonstrated that hospitals did not safely and effectively manage biologic implants, with the majority of hospitals having no systems in place at all, especially for processing recalls.

Tissue Management Lifecycle



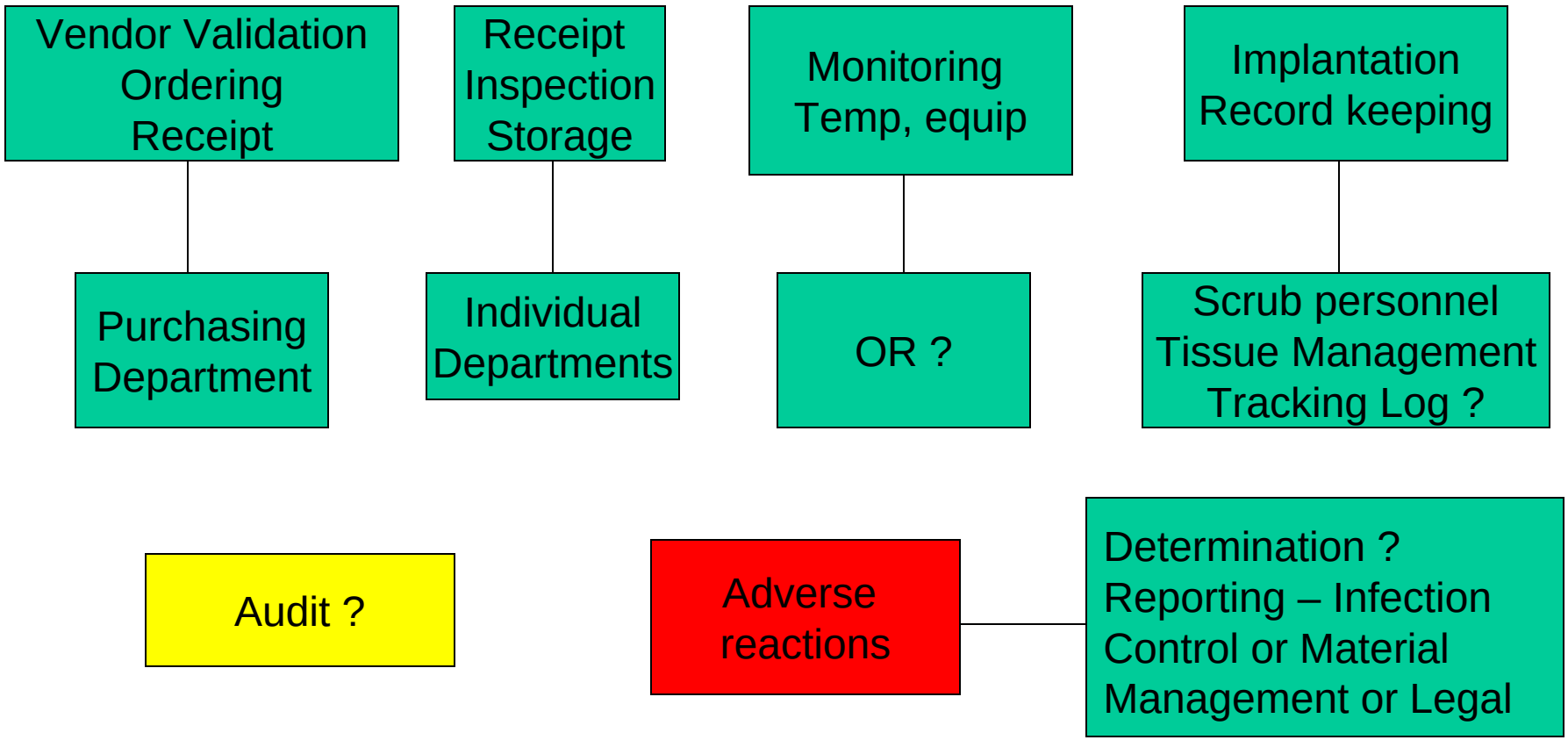
Organizational Design to Meet The Joint Commission Standards



Who Controls Tissues in Hospitals?

- In a study by the CDC surgical departments had responsibility for tissue use (76%) followed by the blood bank (51%).
- In some hospitals blood bank managed certain tissues while surgery handled others. Usually in those hospitals where surgery had responsibility this did not include stem cells.
- Infection control departments were most commonly the responsible party for adverse reaction reporting.

Tissue Management in Most Hospitals

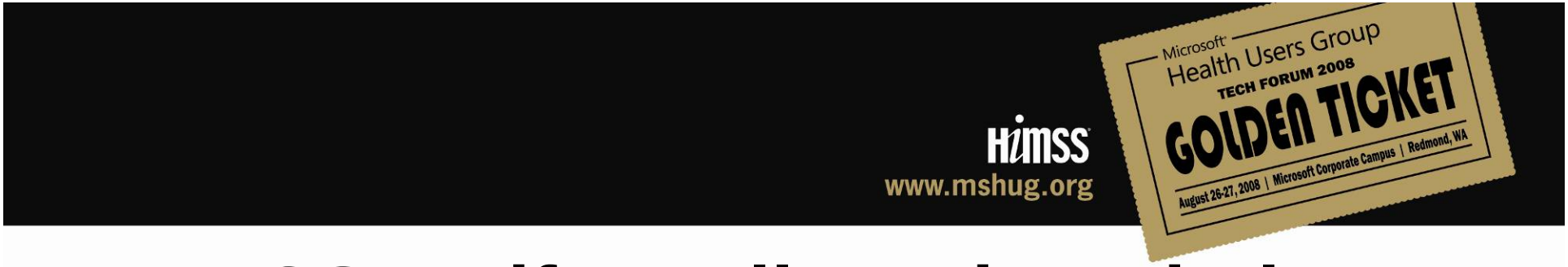


The Solution

- BSI drew from our tissue banking expertise and experience and applied for a patent on a tissue management system that automates and comprehensively manages a hospital's tissue program.
- We partnered with Alto Consulting (MS Gold Partner and ISV) to develop TRACS 4 Life™.

TRACS 4 Life™ Overview

- Web-based
  - Two hosting options: On-premise and Internet
- Microsoft platform: SharePoint 2007, SQL Server 2005 and SQL Report Services
- HIPAA compliant
- Full implementation, maintenance and support
- User friendly and intuitive
- Customizable
- Cost effective



TRACS 4 Life™ allows hospitals to:

- Ensure patient safety and achieve regulatory compliance by managing tissues to the highest standards.
- Easily track and trace receipt, transfer, issuance, implantation/explantation, adverse reaction and recall of tissue products.
- Facilitate multi-departmental involvement in the management of tissue and other implants.
- Monitor inventory with expiratory warnings providing considerable savings in lost & out-dated products

Key Features of TRACS 4 Life™ that meet and exceed Joint Commission tissue standards

- Track all tissue products from receipt into a facility through final disposition
- Trace tissue product issuance, handling, movement, storage temperatures and implantation
- Link product unique ID to patient's clinical record (FMP)
- Provide comprehensive product recall processes
- Supply defined, easy to follow steps for the investigation of adverse reactions/look-backs
- Track products used in tissue preparation & reconstitution
- Record product quality checks (package integrity and temperature)
- Document supplier FDA registration and state licensure (if applicable) or accreditations (AATB etc.)

Additional Functionalities

- Complete inventory management functionalities, including consignment par levels and vendor utilization
- Non-biologic implant tracking
- Manufacturers' barcodes are scanned for tracking
- Visual alert if expired tissue is scanned for implantation
- Product inserts can be posted in SharePoint for immediate reference
- Identifies staff members involved and tasks performed in tissue management process, along with dates and times of actions taken

TRACS 4 Life™ Implementation

- Typically completed in 4-6 weeks
- Interactive, on-line implementation plan
- Three phases of implementation:
  - Phase 1: introduction and information gathering
  - Phase 2: go-live with on-site training
  - Phase 3: post implementation support

TRACS 4 Life™ Product Evolution

- Track and trace biologic and non-biologic implants
- Integration into hospital systems (e.g. purchasing, ADT and clinical documentation)
- New modules: Autologous tissue, Cellular therapies, Breast milk and Reproductive tissues
- Back-end Services: Electronic tissue product ordering, Electronic delivery of product usage information and Direct importing of recall information

Summary

- TRACS 4 Life™ provides a comprehensive solution to well defined industry problem
- TRACS 4 Life™ is driven by patient safety and regulatory compliance
- TRACS 4 Life™ utilizes SharePoint 2007, SQL Server 2005 and SQL Report Services
- TRACS 4 Life™ is user friendly, easy to implement and cost effective
- TRACS 4 Life™ is not a static product; new modules in development

Thank you!

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