Implementação de um Banco de Tecidos

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Porto - 2 Junho 2017
Needs

- Transplantation is an effective and well-established treatment that can significantly benefit citizens facing illness, disability or premature death.
- Demand for organs for transplantation continues to exceed supply.
- Despite the improvements in donation and transplantation outcomes, countries have not met the increasing demand for organs transplantation.
General goals

• To optimise every donation opportunity (multiorgans, tissues and cells)
• To maximise donation rates, increasing the capability and capacity within the health system
• To promote organ and tissue donation, building community awareness and stakeholder engagement
• To implement safe, ethical and effective organ and tissue donation and transplantation systems
• To promote international cooperation to share best practice
• To promote financial sustainability
Exemplo de estrutura (Barcelona)

Consell d'Administració

Comissions del Consell d'Administració

Direcció Gerència

Direcció Adjunta a Gerència

R+D+I

Comunicació

Direcció de Màrqueting i Vendes

Direcció de Persones i Valors

Direcció de Serveis Generals

Direcció de Tecnologies Informació i Comunicació

Direcció Assistencial Central

Direcció Assistencial Territorial

Direcció de Banc de Teixits

Econòmico-financera

Qualitat i Medi Ambient

Planificació i Control de Gestió

Direcció de la Divisió de la Sang

Direcció de la Divisió Diagnòstica

Direcció de la Divisió de Teràpies Avançades

Vall d'Hebron/Clinic

Bellvitge

Badalona

Sant Pau

Catalunya Central

LLeida

Girona

Tarragona/Terres de l'Ebre

BPH

Sang

Llet Materna

Biobanc
AMERICAN ASSOCIATION OF TISSUE BANKS
STANDARDS FOR TISSUE BANKING -1

• A1.000 ACCREDITATION

• A2.000 DEFINITIONS OF TERMS

• B1.000 GENERAL INSTITUTIONAL REQUIREMENTS
  – B1.100 Purpose, Institutional Identity, and Affiliations
  – B1.200 Governing Body
  – B1.300 Medical/Scientific Support
  – B1.400 Satellite Facilities
  – B1.500 Multi-Facility Tissue Banking
    • B1.510 Written Agreements/Contracts
    • B1.520 On-Site Inspections
      – B1.521 Inspections/Audits of Other Facilities
  – B1.600 Contracted and Non-contracted Laboratory Services

• B2.000 FUNCTIONAL COMPONENTS OF A TISSUE BANK
  B2.100 Management Responsibility
  – B2.110 Quality Policy
  – B2.120 Organization
    • B2.121 Responsibilities and Authority
    • B2.122 Resources
    • B2.123 Management Representative
  – B2.130 Management Review
  – B2.140 Technical Policies and Procedures
  – B2.150 Quality Assurance Program

B2.200 Medical Director
  B2.210 Qualifications
  B2.220 Responsibilities
  B2.221 Donor Suitability Criteria
  B2.222 Adverse Outcomes
  B2.223 Confirmed Positive Test Results

B2.300 Technical Staff
  B2.310 Qualifications
  B2.320 Responsibilities

B2.400 Quality Assurance Program
  B2.410 Staff Qualifications
  B2.420 Staff Responsibilities

C1.000 RECORDS MANAGEMENT
  C1.100 General
  C1.110 Required Processing Documentation
  C1.120 Electronic Records
  C1.200 Availability for Inspection
  C1.300 Retention
  C1.400 Traceability
  C1.500 Revisions

C2.000 CONSTRUCTION OF RECORDS

C3.000 DONOR RECORDS TO BE MAINTAINED

C4.000 PROCESSING RECORDS TO BE MAINTAINED BY OTHERS
D1.000 GENERAL POLICIES FOR TISSUE RECOVERY OR COLLECTION

ORGANIZATIONS
  D1.100 Monetary Compensation or Other Valuable Consideration to Donors

D2.000 AUTHORIZATION
  D2.100 Requirements
  D2.200 Conditions
  D2.300 Signatures and Documentation
    D2.310 Document of Gift
    D2.320 Document of Authorization
    D2.330 Methods of Obtaining Authorization
  D2.400 Core Elements for Authorization
  D2.500 Notification of Gift
  D2.600 Services to Donor Families

D3.000 INFORMED CONSENT FOR LIVING DONORS
  D3.100 Requirements
  D3.200 Conditions
  D3.300 Signatures and Documentation
    D3.310 Methods of Obtaining Informed Consent
  D3.400 Core Elements for Informed Consent
D4.000 DONOR SUITABILITY
   D4.100 General
   D4.200 Assessment
      D4.210 Physical Assessment
         D4.211 Physical Examination
      D4.220 Donor Risk Assessment
         4.221 (R) Family History and Genetic Background
      D4.230 Relevant Medical Records Review
      D4.240 Donor Autopsy Report

D4.300 (A) Disease Screening
   D4.310 Infections
   D4.320 Miscellaneous Adverse Conditions
   D4.330 Risk Factors
   D4.340 Malignancies

D4.350 Blood Tests
   D4.351 Specimens
   D4.352 Plasma Dilution
   D4.353 Infectious Disease Testing
   D4.354 Required Infectious Disease Tests
   D4.355 Interpretation of Infectious Disease Test Results
   D4.356 Disclosure and Availability of Positive Infectious Disease Test Results
   D4.357 Archived Samples

D4.360 (R) Repeat Testing of Living Donors
D4.370 (R) Semen Analysis
D4.400 Age Criteria
D4.500 Information Sharing

D5.000 RECOVERY AND COLLECTION POLICIES AND PROCEDURES
   D5.100 Reagents, Supplies, Materials and Equipment
   D5.110 Stock Rotation
   D5.200 Donor Identification
   D5.210 Verification Procedures
   D5.211 Confirmation
   D5.212 Donor Identity
D5.300 Tissue Recovery and Collection — General
   D5.310 Recovery
   D5.320 (R) Collection

D5.400 Time Limits for Tissue Recovery

D5.500 Recovery Environment
   D5.501 Recovery Site Suitability Parameters
   D5.510 Recovery Cleansing and Preparation
   D5.520 Recovery Technique
   D5.521 (MS, OA, S, SB) Cultures Obtained at Recovery

D5.600 Recovery Records

D5.700 Post-Recovery Labeling and Handling

D5.800 Transportation Following Recovery

D5.900 Post-Recovery Reconstruction of a Deceased Donor

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E1.000 PROCESSING, PRESERVATION, QUARANTINE AND STORAGE—GENERAL
   E1.010 Receipt of Tissue at Processing/Storage Facility

   E1.020 Processing Environment

   E1.030 Processing Methods
      E1.031 (C, V) Documentation of Tissue Condition
      E1.032 Temperature Limits
      E1.033 Time Limits for Processing and Preservation Phases
      E1.034 (C, V, S) Prevention of Matrix Deterioration
      E1.035 (C, V, OA, R, S) Additives

   E1.040 Sterilization/Disinfection of Tissue
      E1.041 Non-Terminal Irradiation
      E1.042 Terminal Sterilization by Irradiation
      E1.043 Sterilization by Other Methods
      E1.044 (MS) Disinfection by Chemical Agents
      E1.045 (MS) Other Disinfection Agents

   E1.050 Tissue Evaluation
E1.060 Tissue Preservation/Cryopreservation
   E1.061 Techniques
   E1.062 (C, V) Control-Rate Freezing: Surrogate Packages
   E1.063 (C, V, S) Termination of Freezing Program
   E1.064 (C, V, S) Freezing Profile
   E1.065 (MS) Lyophilization
   E1.066 (MS) Dehydration
   E1.067 Freezing Tissue
   E1.068 (OA, MS) Cryopreservation
   E1.069 (MS) Chemical Preservation

E1.100 Tissue Identification

E1.200 Pooling
   E1.210 Tissue Cross-contamination

E1.300 Reagents, Supplies, Materials and Equipment
   E1.310 Stock Rotation

E1.400 Tracing of In-Process Tissue

E1.500 Tolerance Limits of Processed Tissue
   E1.510 Specimen Sizing
   E1.520 (MS) Calcium Residuals: Demineralized Bone

E1.600 In-Process Controls

E1.700 Processing and Preservation Records

E1.800 In-House Laboratory Testing
   E1.810 Laboratory Records
   E1.820 Laboratory Controls

E2.000 CONTAINERS
   E2.100 Physical Properties
   E2.200 Receipt of New Shipments
   E2.300 Storage
   E2.400 Integrity and Sterility
   E2.500 Visual Inspection

E3.000 QUARANTINING
   E3.100 Quarantine Areas
   E3.200 Situations Requiring Quarantine
   E3.300 Labeling Quarantined Tissue
   E3.400 Quarantine Records
E4.000 STORAGE

E4.100 Storage Temperatures
   E4.110 Refrigerated Tissue
   E4.120 Frozen and Cryopreserved Tissue
   E4.130 (MS) Lyophilized/Dehydrated Tissue
   E4.140 Monitoring Storage Temperatures
   E4.141 Storage Conditions for Commonly Transplanted Human Tissue
   E4.150 Emergency Transfers

E4.200 Expiration Date/Storage Period
   E4.210 Refrigerated Tissue
   E4.220 Frozen and Cryopreserved Tissue
   E4.230 (MS) Lyophilized/Dehydrated Tissue

E4.300 Segregation of Tissue

F1.000 TISSUE RELEASE—GENERAL REVIEW REQUIREMENTS
   F1.100 Donor Suitability Review
   F1.200 Technical Review
   F1.300 Quality Assurance/Quality Control Review
   F1.310 Review of On-Site Processing Records

F2.000 OTHER RELEASE
   F2.100 Tissue Release Based on Tissue Utility
   F2.200 (R) Special Circumstances in Release of Reproductive Tissues
   F2.300 Shipping Reproductive Tissue in Quarantine

F3.000 TISSUE FAILING REVIEW PROCESS—GENERAL REQUIREMENTS
   F3.100 Unsuitable Donors
   F3.200 Technical or Quality Assurance Assessments

F4.000 TISSUE RELEASE—GENERAL
   F4.100 Release to Distribution Inventory
   F4.200 Transfer to Other Inventory Locations
G1.000 LABELS AND LABELING
G1.100 Nomenclature
G1.200 Label List
G1.300 Labeling Integrity
G1.400 Claims

G2.000 LABELING PROCESS
G2.100 General Requirements
G2.200 Re-Labeling
G2.300 Controls—General
   G2.310 Label Inspection
   G2.320 Label Storage
   G2.330 Labeling Process Controls—
      Obsolete Labels
   G2.340 Tissue and Container Visual Inspection

G3.000 LABELING INFORMATION
G3.100 Container Labels
   G3.110 Design
   G3.120 Content
   G3.130 Additional Labeling Requirements
G3.200 Summary of Records and Package Insert
   G3.210 Summary of Records Content
   G3.220 Package Insert Content
G3.300 Transport Package Label Content
   G3.310 Domestic Shipments
   G3.320 International Shipments

H1.000 DISTRIBUTION AND DISPENSING—GENERAL
   H1.010 Solutions
H1.100 Tissue Distribution and Dispensing Restrictions
   H1.110 (R) Client Depositor Authorization
   H1.120 (R) Reproductive Tissue Distribution Restriction
   H1.130 (R) Donor Conceived Offspring Limitations
H1.200 Transfer of Tissue to Other Tissue
   Banks/DispensingServices
H1.300 Requests for Donor Status and Tissue Processing
   Information
H1.400 Distribution Records
   H1.410 Responsibility
H2.000 TISSUE FOR RESEARCH—GENERAL POLICIES AND PROCEDURES
   H2.100 Written Requests
   H2.200 Review and Approval

H3.000 PACKAGING AND SHIPPING
   H3.100 Integrity
   H3.200 Tissue Storage Environment
   H3.300 Validation and Expiration of Transport Container
   H3.400 Quality Control
      H3.410 (C, V) Residual Levels in Packaging
   H3.500 Final Inspection
   H3.600 Transportation

H4.000 RETURN OF TISSUE
   H4.100 Temperature Records

H5.000 CORRECTIONS AND REMOVALS — GENERAL
   H5.100 Circumstances That May Require Correction or Removal
   H5.200 Notification Responsibilities
   H5.300 Handling of Tissue
   H5.400 Reporting Requirements
   H5.500 Correction and Removal Records
J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)
   J1.100 Identification and Control
   J1.200 Contents
   J1.300 Implementation
   J1.400 Modifications
   J1.500 References
   J1.600 Annual Review
   J1.700 Staff Access and Review
   J1.800 Inspections
   J1.900 Archives

J2.000 TECHNICAL AND QUALITY ASSURANCE STAFF—TRAINING/CONTINUING EDUCATION
   J2.100 Training
   J2.200 Competency
   J2.300 Continuing Education
   J2.400 Training Records

J3.000 SAFETY PRACTICES
   J3.100 Work Environment
   J3.200 Procedures
   J3.300 Hazardous Materials Training
   J3.400 Universal Precautions
   J3.500 Immunization
   J3.600 Hazardous Waste Disposal
   J3.700 Personnel
      J3.710 Attire
      J3.720 Infections

J4.000 FACILITIES
   J4.100 General
   J4.200 Designated Space
      J4.210 Routine Cleaning
   J4.300 Environmental Monitoring
   J4.400 Security

J5.000 EQUIPMENT
   J5.100 Selection
   J5.200 Operation
   J5.300 Qualification and Maintenance
      J5.310 Requalification/Recalibration
   J5.400 Decontamination/Sterilization
   J5.500 Storage Unit Identification
K1.000 QUALITY ASSURANCE PROGRAM
  K1.100 Basic Elements
  K1.200 Qualification, Verification, and Validation Requirements
    K1.210 (C, V) Validation of Shipping Containers
    K1.220 (C, V) Validation Procedures—Packaging and Freezing Protocols
  K1.300 Purchasing Controls

K2.000 QUALITY CONTROL PROGRAM
  K2.100 Proficiency Testing
  K2.200 Microbiological Tissue Cultures
    K2.210 Pre-Sterilization/Pre-Disinfection Cultures
    K2.220 Final/Pre-Packaging
  K2.300 (C, V) Testing for Residues
  K2.400 Other Quality Control Procedures
    K2.410 (MS) Lyophilized/Dehydrated Tissue
    K2.420 Annual Calibrations

K3.000 MICROBIOLOGIC TESTING
  K3.100 Transport Medium
  K3.200 Selection of Growth Medium
    K3.210 Quality Control of Growth Medium
  K3.300 Microbiologic Subcultures

K4.000 INVESTIGATIONS
  K4.100 Errors and Accidents
  K4.200 Complaints
  K4.300 Adverse Outcomes
    K4.310 Reporting

K5.000 INTERNAL AUDITS

K6.000 ELECTRONIC SYSTEMS CONTROLS
  K6.100 Authorized Access
  K6.200 Error Reduction
  K6.300 Backup Files
  K6.400 Security

L1.000 TISSUE DISPENSING SERVICES—GENERAL
  L1.100 Responsibilities

L2.000 STORAGE
  L2.100 General
  L2.200 Equipment
  L2.300 Labeling

L3.000 RELEASE
  L3.100 Dispensing
  L3.200 Release to Another Tissue Dispensing Service or Tissue Distribution Intermediary
  L3.300 Tissue Disposal
  L3.400 (R) Return of Tissue
AMERICAN ASSOCIATION OF TISSUE BANKS
STANDARDS FOR TISSUE BANKING -11

L4.000 RECORDS
L4.100 Tissue Receipt Records
L4.200 Dispensing Records
L5.000 ADVERSE OUTCOMES
L6.000 CORRECTIONS AND REMOVALS

M1.000 TISSUE DISTRIBUTION INTERMEDIARIES—GENERAL

M2.000 STORAGE
M2.100 General
M2.200 Equipment
M2.300 Labeling
M3.000 DISTRIBUTION—GENERAL
M3.100 Tissue Distribution Restrictions
M3.200 Transfer of Tissue to Other Tissue Banks/Dispensing Services
M3.300 Requests for Donor Status and Tissue Processing Information
M3.400 Distribution Records
M3.500 Tissue Disposal

M4.000 PACKAGING AND SHIPPING
M4.100 Tissue Storage Environment
M4.200 Validation and Packaging Expiration
M4.300 Quality Control
M4.400 Final Inspection
M4.500 Transportation

M5.000 RETURN OF TISSUE

M6.000 CORRECTIONS AND REMOVALS — GENERAL
M6.100 Correction and Removal Records

M7.000 RECORDS
M7.100 Tissue Receipt Records
M7.200 Distribution Records

M8.000 ADVERSE OUTCOMES

Appendix I: REQUEST FOR VARIANCE FROM STANDARDS

Appendix II: CRITERIA FOR PREVENTING TRANSMISSION of RCDADs (Relevant Communicable Disease Agents and Diseases) THROUGH TRANSPLANTATION OF HUMAN TISSUE

Reference I: AATB ACCREDITATION POLICIES FOR TRANSPLANT TISSUE BANKS.....(not included in this version; see the AATB website)

Reference II: AATB GUIDANCE DOCUMENTS .......(not included in this version; see the AATB website)
What can be retrieved
MEDICAL APPLICATIONS

Normal tissue can be used as an allograft.

EXAMPLES

Cornea transplants
• Corneal transplantation
  Storage time for transplantation limited to 1–4 weeks.
• Corneal lenticules

Reconstruction due to cancer or trauma
• Breast reconstruction
• Facial reconstruction

Skin transplants
• Covering for severe burns
• Covering for diabetic foot ulcers

Heart valve replacement
Most common:
• Mitral valve replacement
• Aortic valve replacement
• Valve replacement in children with congenital heart disease

Vascular grafts/bypasses
• Limb-saving arterial surgery
• Femoral veins, saphenous veins and arterial grafts intended as A-V shunts

Amniotic membrane transplants
• Used in ophthalmic surgeries, e.g. as a permanent or overlaid graft in corneal surface reconstruction
• Stem cells are cultivated in vitro on amniotic membrane to treat limbal stem cell deficiency
• Used as skin substitute (e.g. in burn surgery)

Hematopoietic stem cells (HSCs)
• HSCs are usually derived from bone marrow, peripheral blood or umbilical cord blood. Autologous or allogeneic HSC transplantation is used to treat a wide spectrum of haematological, and increasingly, non-haematological disorders.

Cartilage, ligament or tendon allografts
• Anterior cruciate ligament repair
• Meniscal replacement
• Bladder slings

Bone allografts
• Spinal fusion
• Ridge augmentation in dental procedures
• Reconstruction of bone defects caused by cancer or trauma

Cosmetic surgeries & procedures without medical indication
• Lip augmentation
• Penis enlargement
• Wrinkle smoothing via collagen injection
Access to human tissues for research and product development

From EU regulation to alarming legal developments in Belgium

"Human tissues for research are said to be worth more than diamonds, being valued at US $500/g."

... the term “reasonable fee” has never been defined and this loophole is now being exploited to turn altruistic donations into profits"

In contrast to the USA, Europe initially adopted a more restrictive attitude. Most of Europe’s tissue banking activity remains at hospital tissue banks, while some specialised activities, such as tissue engineering, are outsourced to biotechnology companies. This situation has created tension between the altruistic principles of hospital tissue banks and industry’s profit-oriented principles. Meanwhile, industry lobbying and the political desire to promote the growth of biotechnology markets and jobs have led to increasingly business-oriented legislation controlling human tissue handling in the EU. This shift has now gone so far that in some legislations, the risk arises that the interests of industry could take precedence over the interests of patients and research.
Legal framework for tissue donation
3 EC Directives

- Directive 2004/23/EC, which provides the framework legislation

- Technical Directives
  - 2006/17/EC
  - 2006/86/EC, which give detailed requirements.

The Advanced Therapy Medicinal Product (ATMP) Regulation (EC) No 1394/2007 (hTEPs human tissue-engineered products)
the legal concept of “Tissue Establishment” was introduced, which expands on the conventional concept of a tissue bank. Companies with an accreditation as a Tissue Establishment would thereby obtain direct access to human tissues and cells. These regulations have established a crucial legal difference between organs and tissues: human tissues are legally tradable goods in a global market.

EU splits responsibilities allowing diversity

This commercialisation of human tissues raises several ethical and public health issues. Although acknowledging the legitimacy of these concerns, the EC invoked the principle of subsidiarity—whereby the EU only takes action in areas, which fall within its exclusive competence—to relegate ethical and public health issues to the Member States.
Belgian accepted Presumed consent to donation (opting –out)

“If Belgian citizens were to suspect that donated tissues become part and parcel of profit-maximizing activities, they might be more likely to exercise their right to opt-out”

Belgian Banks for Human Body Material have already invested heavily in clean room facilities and are getting ready to produce hTEPs in compliance with GMP requirements, even though there is no evidence that these investments will actually result in any significant improvement to the quality or safety of their grafts.

“Differences in consent to tissue donation, such as opting-in versus opting-out, create opportunities for exploitation by companies that lack ethical responsibility”
Article 21 of the 1997 Council of Europe Convention of Human Rights an BioMedicine provides that it is not permissible for the human body or its parts as such to give rise to profits.

However, it does not prevent specific commercial activities, such as:

the patenting of human body material in
- isolated
- purified or
- slightly modified form

“While human tissue itself cannot have human dignity, human dignity is nevertheless concerned when human tissue is involved”
Countries such as Belgium, which have an “opt-out” rule or presumed consent regime, are therefore interesting for brokers and corporate actors to get access to human tissue material for processing into highly profitable products.

In this way, the values of solidarity and the common good that are supposed to underlie presumed consent are increasingly being eroded.

A wide variation in prices exists, ranging from hundreds to thousands of dollars for the same product.

In sports medicine, tendon and bone allografts, for instance, fetch higher prices in areas with a flourishing sports culture than tendon and bone products for general orthopaedics.

A striking example is the processing of human skin, the gold standard for the treatment of severe burns, into cosmetic products without medical indication, such as penis widening or lip enhancements, which fetch much higher prices than analogues for burn treatments.

US burn centres were reportedly struggling to obtain skin because local tissue banks are committing all their donated skin to firms that market products for plastic and cosmetic surgery.
Presumed consent relies on citizens trust

Presumed consent = opt-out system

Portugal, Spain, Belgium, Austria, laws make organ donation the default option at the time of death people must explicitly “opt out” of organ donation.

In these so-called opt-out countries, more than 90% of people donate their organs.

Yet in countries such as U.S. and Germany, people must explicitly “opt in” if they want to donate their organs when they die.

In these opt-in countries, fewer than 15% of people donate their organs at death
Ideally, the procurement and allocation of human tissues and cells should be controlled and facilitated by (inter)national non-profit organisations, comparable to organ donation and transplantation foundations such as Eurotransplant and Swiss Transplant. An excessive commercialisation of human body material could lead to a loss of trust in the transplantation field and could put at risk the successful “opting out” or “presumed consent” donation systems in some EU Member States. Policymakers seem enamoured by the methods and rhetoric of industry, leading them to neglect the interests of donors and their families and eroding the public values underlying the healthcare system.
Access to human tissues for research and product development

From EU regulation to alarming legal developments in Belgium

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DOI 10.15252/embr.201540070 | Published online 7 April 2015
Análise económica

• Custo Total = custos variáveis + Custos fixos

• **Custos variáveis ou custos directos:**
  – Screening de doadores
  – Colheita de tecidos
  – Transporte
  – Análises
  – Processamento
  – Armazenamento
  – Distribuição
  – Controlo de qualidade

• **Custos fixos:**
  – Investimentos de capital, construção de salas brancas e instalações, equipamento e aparelhos
  – Salários de pessoal (administração, médico, técnicos de laboratório, administrativos, auxiliares)
  – Serviços contratados (empresas de limpeza, manutenção de instalações, manutenção de equipamentos)
  – Electricidade, climatização, água
Actividades e custos atribuíveis à produção Screening e Colheita

– Localização de dadores
– Obtenção do consentimento/confirmação RENNDA
– Transporte de equipas de colheita
– História clínica e comportamental
– Salários das equipas de procura e colheita
– Consumíveis da colheita

Comparaçao destes custos com o valor pago pelos tecidos, se forem comprados no exterior
Actividades e custos atribuíveis à produção

Estudo Analítico

– Parcialmente diluído em dadores multiorgão
– Testes serologia vírica
– Testes microbiológicos
– Testes específicos para os tecidos (Lâmpada de fenda)
– Autópsias
– Testes follow-up dos dadores vivos
– Consumíveis
– Salários do pessoal do banco de tecidos atribuídos ao tempo gasto nas actividades analíticas
Actividades e custos atribuíveis à produção
Processamento

- Salários atribuídos ao tempo gasto para transformar o tecido inicial no produto final (corte, invólucro, marcação)
- Identificação do tecido e codificação
- Esterilização
- Refrigeração
- Congelação controlada
- Cultura
- Consumíveis usados no processamento
Actividades e custos atribuíveis à produção
Armazenamento e distribuição

• Salários atribuídos ao tempo gasto para
  – armazenamento,
  – embalamento do tecido para transporte,
  – envio do tecido

• gastos com consumíveis
Controlo de Qualidade

• Salários e custos com
  – Revisão médica,
  – Calibração de equipamentos
  – Manutenção Preventiva
  – Monitorização
  – Desenvolvimento de standards
  – Training e educação
  – Auditorias
  – Investigação e desenvolvimento
Análise custo benefício

• Criação e manutenção de
  – Centros de Processamento e Criopreservação
  – Centros de recolha

• Versus

• Colaboração internacional (ibérica por exemplo), com sistema idêntico de consentimento presumido, nos tecidos com excedentes nesses países
Spain success
(internet search)

• Organ donations: How the Spanish transplant system works - BBC News
  www.bbc.com/.../organ-donations-how-the-spanish-transplant-sys...
  On Tuesday, Wales becomes the first UK nation to introduce a system where consent is assumed unless people have opted out. Spain has the highest organ ...

• Margaret McCartney: When organ donation isn't a donation | The BMJ
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  28/02/2017; 356 doi: https://doi.org/10.1136/bmj.j1028 (Published 28 ...
  “Soft opt-out boosts donation in Wales,” wrote the BMA.1 “Dozens saved' in six ...
  It’s worth noting that, in Spain—the high achiever of the organ donating ...

• Opt-out proposal for organ donation presumes consent - PressReader
  https://www.pressreader.com/uk/the.../20170511/2820118522775...
  Opt-out proposal for organ donation presumes consent ... The Scotsman - 2017-05-11 - Friends Of The Scotsman / Health - ...
  Spain has significantly higher rates of organ donation than Scotland, although an opt-out system has operated for ...

• Increasing organ donation rates: is legislation enough? - The Lancet
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  02/04/2017 - On Jan 1, 2017, France implemented a hard opt-out policy for organ donation. ...
  “consent from a potential organ donor's family if the individual had ...
  Organización Nacional de Trasplantes in Spain, which has achieved the ...

• Spain Organ Donation 2017 | BookInfos.org - Read eBooks ...
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• How Spain became the world leader in organ transplants - The Local
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• France’s New Opt-Out Organ Donation System Is a Good Idea - NYMag
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  03/01/2017 - Those who do wish to opt out of organ donation can fill out a form online, ...
  for example, Spain, which at 35.7 per 1 million people is what Leins

• Etc........
**Escândalo com a Biomedical Tissue Services**

**N.Y. / REGION**

*Michael Mastromarino, Dentist Guilty in Organ Scheme, Dies at 49*

*By DANIEL E. SLOTNIK*  
*JULY 8, 2013*

- He established a network of undertakers, whom he paid up to $1,000 per corpse, and soon took on assistants and formed a business based in New Jersey, Biomedical Tissue Services. He reportedly made $10,000 to $15,000 per body. ...

- But Dr. Mastromarino harvested organs and tissue from bodies without consent from the survivors, the authorities said, and removed material from people with cancer, H.I.V. and other diseases. He then forged paperwork, including consent forms and death certificates, to make the cause of death and age acceptable.
Onde está o histórico dos registos em Portugal?

- **BioMedical Tissue Services Scandal | Lawsuits, Lawyers | Side Effects: Infected Tissue, Infected Body Part, Risk Of Developing Infectious Diseases | Owner Accused, Stealing Body Parts, Forged Documents**

- **Biomedical Tissue Services (BTS)** proprietor Michael Mastromarino has been accused of stealing body parts from approximately 1,077 cadavers without relatives’ permission from more than 30 funeral homes. Mr. Mastromarino then sold the unscreened tissue for profits, and forged documents to cover his tracks. In February 2006, the Brooklyn District Attorney in a 122-count indictment charged Mastromarino and three additional workers.

- New York Police Commissioner Raymond Kelly stated in February 2006 that investigators had identified **funeral homes in northern New Jersey, New York and one in Philadelphia had taken part in the body snatching**. An ex-Biomedical Tissue worker told the Philadelphia Daily News in a February 2006 interview that he made approximately a dozen trips to the Louis Garzone Funeral Home in late 2004. During these trips, Kevin Vickers, the ex-Biomedical Tissue Services (BTS) worker said two to three bodies were harvested during each trip.

- Authorities in New York have dug up more than a dozen bodies to verify that parts were illegally harvested. In some instances plastic hardware-store tubing would found as replacements to bones. It is believed that funeral home operators accepted money from the BioMedical Tissue Services (BTS) in exchange for ignoring obviously forged death certificates and consent forms. The body parts and tissue in question have been distributed throughout the country and used in thousands of operations.

- **Biomedical Tissue Services sold these illegal body parts to several large companies including Lifecell Corp., Regeneration Technologies, Inc., Tutogen Medical, Inc., SpinalGraft Technologies, LLC, Lost Mountain Tissue Bank and The Blood & Tissue Center of Central Texas. The FDA and most of the companies involved have not disclosed the number of patients that received the untested parts and tissue.**
Portugal importou tecidos da **BioMedical Tissue Services**?

- **In New York, a Grisly Traffic in Body Parts**
  - By Michael Powell and David Segal
  - Washington Post Staff Writers
  - Saturday, January 28, 2006

  NEW YORK -- Hundreds of very live Americans are walking around with pieces of the wrong dead people inside of them.
  
  A macabre scandal has spread from a body-harvesting lab in New Jersey to hospitals as far away as Florida, Nebraska and Texas as hundreds of people discover that they have received tissue and bone carved from looted corpses, not least the cadaver of Alistair Cooke, the late and erudite host of PBS's "Masterpiece Theatre."
  
  The Brooklyn district attorney and federal Food and Drug Administration inspectors are investigating dozens of funeral homes in New York City and Biomedical Tissue Services Ltd. of Fort Lee, N.J., which is run by a former dentist who, his lawyer acknowledges, abused intravenous pain medications while with patients.
  
  The former dentist came to funeral homes, investigators say, and **extracted bone, tendons and skin from corpses** without the consent of relatives. Later, Biomedical Tissue Services shipped coolers full of tissue to hospitals for surgeries. A dead body can be worth tens of thousands of dollars when it is dissected for parts.
  
  The scandal **raises questions about the safety and proper supervision of a billion-dollar-a-year industry that supplies skin and tissue for 1 million tissue transplants each year**. But patients are most confounded by the skin-crawling fact that no one knows from whom the bone and tissue was harvested.

Daniel George and Son Funeral Home is one of six Brooklyn funeral homes where Biomedical Tissue Services, headed by Michael Mastromarino, below, is alleged to have harvested body parts without permission. As many as **1,000 bodies may have been desecrated**. (Photos By Andrew Theodorakis)
The lack of proper tracking means that by the time problems are discovered some of the manufactured goods can’t be found. When the U.S. Centers for Disease Control and Prevention assists in the recall of products made from potentially tainted tissues, transplant doctors frequently aren’t much help.

'Oftentimes there’s an awkward silence. They say: "We don’t know where it went",' said Dr. Matthew Kuehnert, the CDC’s director of blood and biologics. 'We have barcodes for our [breakfast] cereals, but we don’t have barcodes for our human tissues,' Kuehnert said. 'Every patient who has tissue implanted should know. It’s so obvious. It should be a basic patient right. It is not. That’s ridiculous.'

Since 2002 the U.S. Food and Drug Administration has documented at least 1,352 infections in the U.S. that followed human tissue transplants, according to an ICIJ analysis of FDA data. These infections were linked to the deaths of 40 people, the data shows. One of the weaknesses of the tissue-monitoring system is the secrecy and complexity that comes with the cross-border exchange of body parts.

The Slovaks export cadaver parts to the Germans; the Germans export finished products to South Korea and the U.S.; the South Koreans to Mexico; the U.S. to more than 30 countries. Distributors of manufactured products can be found in the European Union, China, Canada, Thailand, India, South Africa, Brazil, Australia and New Zealand. Some are subsidiaries of multinational medical corporations.

The international nature of the industry, critics claim, makes it easy to move products from place to place without much scrutiny.

'If I buy something from Rwanda, then put a Belgian label on it, I can import it into the U.S. When you enter into the official system, everyone is so trusting,' said Dr. Martin Zizi, professor of neurophysiology at the Free University of Brussels.

Once a product is in the European Union, it can be shipped to the U.S. with few questions asked.

"They assume you’ve done the quality check," Zizi said. "We are more careful with fruit and vegetables than with body parts."
• FDA inspectors also identified deficiencies with RTI's Ukrainian imports when it visited the company's facilities in Florida.

• RTI had English translations, but not original autopsy reports, from its Ukrainian donors, FDA inspectors found during a 2010 audit. Those were often the only medical documents the company used to determine whether the donor was healthy, inspectors noted in their report.

• Security services footage shows harvested human tissues in Ukraine labeled "Made in Germany".

• The company told inspectors it was illegal under Ukrainian law to copy the report. But following the inspection it began maintaining the original Russian-language document along with its English translation.
Futuro

Necessária análise de sustentabilidade dos bancos de tecido existentes

Apertado controlo ético