

APIH/SETS 2017

Implementação de um Banco de Tecidos

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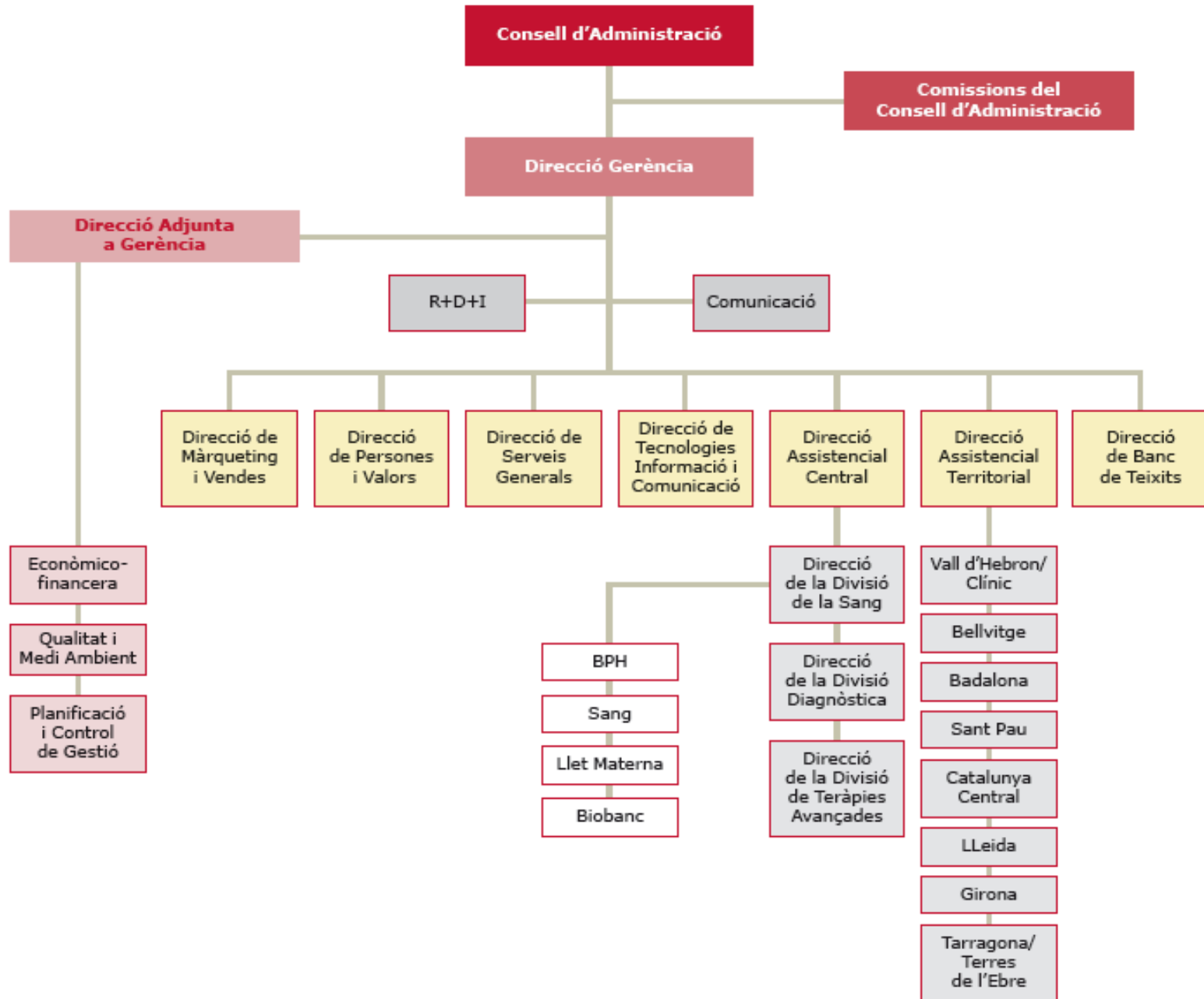
Needs

- 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)



- **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

AMERICAN ASSOCIATION OF TISSUE BANKS STANDARDS FOR TISSUE BANKING -1

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

**AMERICAN ASSOCIATION OF TISSUE
BANKS**
STANDARDS FOR TISSUE BANKING -2

**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

**AMERICAN ASSOCIATION OF TISSUE
BANKS**
STANDARDS FOR TISSUE BANKING -3

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

AMERICAN ASSOCIATION OF TISSUE BANKS

STANDARDS FOR TISSUE BANKING -4

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

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

AMERICAN ASSOCIATION OF TISSUE BANKS STANDARDS FOR TISSUE BANKING -5

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

**AMERICAN ASSOCIATION OF TISSUE BANKS
STANDARDS FOR TISSUE BANKING -6**

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/Dispensing Services**

**H1.300 Requests for Donor Status and Tissue Processing
Information**

H1.400 Distribution Records

H1.410 Responsibility

AMERICAN ASSOCIATION OF TISSUE BANKS STANDARDS FOR TISSUE BANKING -7

AMERICAN ASSOCIATION OF TISSUE BANKS *STANDARDS FOR TISSUE BANKING -8*

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

**AMERICAN ASSOCIATION OF TISSUE BANKS
STANDARDS FOR TISSUE BANKING -9**

**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**

AMERICAN ASSOCIATION OF TISSUE BANKS
STANDARDS FOR TISSUE BANKING -10

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)**

ORGANS

Warm and cold ischemic phases before transplantation need to be kept to a minimum.

Thymus

Lungs

Heart

Liver

Pancreas

Kidneys

Intestine

HUMAN TISSUES & CELLS

Tissues and cells – normal and pathological – are banked for transplantation, research and other uses. Short to long term preservation/storage is possible.

Dura mater

Sclera

Cornea

Eardrum

Teeth

Periodontal ligament
stem cells

Neurons

Gital cells

Blood vessels

- Thoraco-abdominal aorta
- Pulmonary artery
- Hemipulmonary artery
- Pulmonary patch
- Aortic bifurcation with iliac arteries
- Femoral artery
- Femoral veins
- Saphenous veins
- Umbilical cord veins
- ...

Heart valves

- Aortic v.
- Mitral v.
- Pulmonary v.

Pancreatic tissue

Islet cells

Ovarian tissue

Oocytes

Testicular tissue

Spermatozoa

Skin

Keratinocytes

Amniotic membrane

Adipose tissue

Adipose-derived stem cells

Fascia

- Pericardium
- Fascia lata
- ...

Chondrocytes

Cartilage

- Rib costal cartilage
- Knee cartilage
- Lateral meniscus
- Medial meniscus
- ...

Fibroblasts

Collagen

Tendons

- Quadriceps tendon
- Tibialis tendon
- Semitendinosus tendon
- Gracilis tendon
- Peroneus tendon
- Patellar tendon
- Achilles tendon
- ...

Umbilical cord blood

Blood

Bone marrow

Bones

- Cranial bones
- Facial bones
- Ossicles
- Mandible
- Ribs
- Vertebrae
- Pelvis
- Ilium
- Iliac crest
- Hip socket
- Radius
- Ulna
- Hand bones
- Humerus
- Patella
- Femur
- Tibia
- Fibula
- Talus
- Calcaneus
- Foot bones

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

What can be retrieved

MEDICAL APPLICATIONS

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EMBO reports

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 framework for tissue donation, banking and usage in the EU is comprised of three EC Directives: the parent Directive 2004/23/EC, which provides the framework legislation, and two technical Directives, 2006/17/EC and 2006/86/EC, which give detailed requirements. In 2008, the Advanced Therapy Medicinal Product (ATMP) Regulation (EC) No 1394/2007, which covers hTEPs among other things, came into force. Because public health matters fall under the competence of the EU Member States, the Directorate General Enterprise of the European Commission invoked the “common safety concerns in public health” clause, which falls under the auspices of the EC, to create a regulatory environment that would facilitate a market for hTEPs. Pharmaceutical industry standards, such as good manufacturing practice (GMP) and marketing authorisation, were imposed upon the predominantly hospital-based human tissue transplantation field. In

Tissue Establishment versus Tissue Bank

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”

Human dignity and profit

Article 21 of the 1997 Council of Europe Convention of Human Rights on 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”

Different markets, different prices to the same product:
different access to human tissues
Skin deviation to cosmetics

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.

cosmetics rather than medical products.

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

International cooperation of non profit organizations as a solution to maintain Presumed Consent trust

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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 - 4 Service d'Hématologie Expérimentale-Laboratoire de Thérapie Cellulaire Clinique, Université Libre de Bruxelles-Institut Jules Bordet, Bruxelles, Belgium
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 - 6 Faculty of Medicine, Institute of Human Histology, Immunology Centre, University of Liège, Liège, Belgium
 - 7 Centre for Reproductive Medicine, Ghent University Hospital, Gent, Belgium
 - 8 Tissue Bank, Ghent University Hospital, Gent, Belgium
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 - 14 Aix-Marseille Université (AMU), Marseille, France
 - 15 Inserm-Centre d'Investigations Cliniques en Biothérapie (CBT)-510, Marseille, France
 - 16 Centre for Biomedical Ethics and Law, KU Leuven, Leuven, Belgium
 - 17 Burn Wound Centre, Queen Astrid Military Hospital, Brussel, Belgium
 - 18 Department of Philosophy and Moral Sciences, Bioethics Institute Ghent, Ghent University, Gent, Belgium
- DOI 10.15252/embr.201540070 | Published online 7 April 2015

Análise económica

- $\text{Custo Total} = \text{custos variáveis} + \text{Custos fixos}$
- **Custos variáveis ou custos directos:**
 - Screening de dadores
 - 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

Comparação 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](#)
- www.bmj.com/content/356/bmj.j1028 - [Traduzir esta página](#)
- de M McCartney - 2017
- 28/02/2017 - BMJ **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...> - [Traduzir esta página](#)
- **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](#)
- [www.thelancet.com/pdfs/.../PIIS2468-1253\(17\)30037-7.pdf](http://www.thelancet.com/pdfs/.../PIIS2468-1253(17)30037-7.pdf) - [Traduzir esta página](#)
- 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 ...](#)
- bookinfos.org/spain-organ-donation-reb.html
- [Traduzir esta página](#)
- **Organ Donation** Is When A Person Allows Healthy Transplantable Organs And Tissues To Be Some Countries With An **Opt-out** System Like **Spain** (36 Effective ...
- [How Spain became the world leader in organ transplants - The Local](#)
- <https://www.thelocal.es/20170111/how-spain-became-world-lead...>
- [Traduzir esta página](#)
- 11/01/2017 - **Spain** has been the world leader in **organ donation** for the last 25 years and in 2016 it broke its own record for ... 11 January **2017** ... Most importantly **Spain** operates an "**opt-out**" system in which all citizens are automatically ...
- [France's New Opt-Out Organ Donation System Is a Good Idea - NYMag](#)
- nymag.com/.../2017/01/frances-new-opt-out-organ-donation-system-is-a-good-idea.htm...
- 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.....



ORDEM
DOS
MÉDICOS

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.*
-



Michael Mastromarino in 2006, before his arraignment.
Credit Seth Wenig for The New York Times



ORDEN
DOS
MÉDICOS

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.*

- 07-03-2017



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)



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- 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.
- 07-03-2017
- **"They assume you've done the quality check," Zizi said. "We are more careful with fruit and vegetables than with body parts."**



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- **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