The Role of Vigilance and Surveillance: Project NOTIFY

Technical Consultation on Knowledge Sharing and Networking for Human Cell, Tissue and Organ Donation and Transplantation in the Western Pacific Region

Seoul, February 20-21 2014

2010

World Health Assembly Resolution WHA63.22
Human Organ and Tissue Transplantation

- 3. REQUESTS the Director-General:
  - (1) to disseminate the updated Guiding Principles on Human Cell, Tissue and Organ Transplantation as widely as possible to all interested parties;
  - (2) to provide support to Member States and nongovernmental organizations in order to ban trafficking in material of human origin and transplant tourism;
  - (3) to continue collecting and analyzing global data on the practices, safety, quality, efficacy, epidemiology and ethics of donation and transplantation of human cells, tissues and organs;
  - (4) to facilitate Member States’ access to appropriate information on the donation, processing and transplantation of human cells, tissues and organs, including data on severe adverse events and reactions;

2010

World Health Assembly Resolution WHA63.22
Human Organ and Tissue Transplantation

- 2. URGES Member States:
  - [5] to improve the safety and efficacy of donation and transplantation by promoting international best practices;
  - [6] to strengthen national and multinational authorities and/or capacities to provide oversight, organization and coordination of donation and transplantation activities, with special attention to maximizing donation from deceased donors and to protecting the health and welfare of living donors with appropriate health-care services and long-term follow-up;
  - [7] to collaborate in collecting data including adverse events and reactions on the practices, safety, quality, efficacy, epidemiology and ethics of donation and transplantation;
  - [8] to encourage the implementation of globally consistent coding systems for human cells, tissues and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation;

The WHO Wide Initiative for MPHO

1. Standards of Practices Common to MPHO
   - Non commercial nature of the human body and its parts as such
   - Towards a global consensus leading to a formal agreement

2. Universal use of ISBT 128 for all MPHO
   - Information Standards for Blood and Transplant
   - Towards universal use of ISBT128 within 10 years

3. Global vigilance and surveillance
   - NOTIFY project for Vigilance and Surveillance of MPHO
   - Towards using at best the global experience of adverse events and reactions

Vigilance and Surveillance

A Comprehensive Safeguard to Allow Timely Reaction

Definitions – EU and NOTIFY

EU: ‘Serious Adverse Reaction (SAR)’ means an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling, incapacitating or which results in or prolongs, hospitalization or mortality

(NOTIFY: An adverse occurrence that HAS occurred, including a serious adverse reaction in a recipient or in a living donor)

EU: ‘Serious Adverse Event (SAE)’ means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalization or mortality

(NOTIFY: An adverse occurrence that MIGHT lead to harm in a recipient or a living donor)
The NOTIFY project for Vigilance and Surveillance of MPHO services

- Mutualizing the global experience of V&S in MPHO services
  - Risk identification
  - Risk assessment
  - Risk based quality management
  - Risk education
- Promoting V&S as a crucial mechanism of quality and transparency in MPHO services
- Associating professionals, Operators and Competent Authorities
- Demonstrating Transparency
- Deserving trust

The NOTIFY tools

- NOTIFY Website [http://www.notifylibrary.org](http://www.notifylibrary.org)
- NOTIFY Library of didactic cases of events and reactions
  - Donor selection and management
  - Recipient management
  - Quality system - risk based management
- NOTIFY Booklet
- NOTIFY Journal

The NOTIFY Library

- A database of all types of severe adverse events and reactions that have been reported arising from procurement and processing to clinical application of cells, tissues and organs for transplantation as well as of medical products of human origin used in assisted reproduction technologies.

1. A reference for professionals focused on diagnostic and investigation
2. but also providing evidence for donor selection,
3. A source of information for candidate recipients and living donors
4. A reference for risk based quality management systems
5. A database for further study


The NOTIFY Library Operation

- Literature review
- Structured Automated
- Comprehensive
- CNT Secretariat
- Partner organisations
  - Competent Authorities
  - Scientific Professional Societies

Accept

Ad hoc queries
current, and accessible

Analyze new data and modify structured analysis regarding alerting signals etc.

Analysis – structured, searchable, current and accessible

Record of Rejection

Record of justification of Rejection

The NOTIFY Library

- NOTIFY Website: http://www.notifylibrary.org

A sample of the bibliography

Clicking on a single reference

The NOTIFY Booklet

The NOTIFY Library

The NOTIFY Library

The NOTIFY Library

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A sample of the bibliography

Clicking on a single reference

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The NOTIFY Library

The NOTIFY Library
NOTIFY Progress

- Addition of Blood and blood derivatives (attributes, database changes).
- Addition of cases involving IWD (Intervention without disease transmission) and organism transfer without disease.
- Addition of cases involving ethical breaches.
- Portals in national languages.

NOTIFY Journal

1. Editorial Board: Representatives of NOTIFY project and supporting institutions.
2. Advisers: WHO technical staff.
3. Team: WHO PUB staff.

NOTIFY Board of Supporting Institutions

- Health Authorities
- Scientific and professional societies

Thank you

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ISBT 128: Information Standard for Blood and Transplant

Paul Ashford
Executive Director
ICCBBA

ICCBBA Vision and Mission

- Mission: Enhancing patient safety by promoting and managing the ISBT 128 international information standard for use with medical products of human origin
- Vision: Global adoption of ISBT 128 for all medical products of human origin

The Acronyms

- ICCBBA – International Council for Commonality in Blood Bank Automation
- ISBT
  - Derived from ‘International Society of Blood Transfusion’
  - Now interpreted as ‘Information Standard for Blood and Transplant’
  - 128 – ISO character set

Medical Products of Human Origin

- MPHO
  - Blood and blood components/products
  - Cells
  - Tissues – ocular and non-ocular
  - Organs
  - Tissue Engineered
  - Milk
  - Other?

ICCBBA

- International standards organization
- Not-for-profit organization formed in 1994 – celebrating our 20th anniversary!
- US based, UK based Executive Director, global in scope
- Nongovernmental organization in official relations with the World Health Organization
- Small staff (10), large community of expert volunteers (>300)

Common Characteristics of MPHO

- Contain material derived from human donor
- Potential risk of infection
  - Traceability
  - Vigilance and Surveillance
- Ethical issues
  - Consent
  - Exploitation
- Global Governance
  - Encourage self sufficiency
  - Counter transplant tourism
There is a growing consensus on the need for international harmonization of coding and labeling of MPHO:
- Single donor may donate multiple MPHO
- Need for traceability across all products
- Recognized in World Health Assembly Resolution WHA63.22 “Human Organ and Tissue Transplantation” May 2010

Developed for blood transfusion following First Gulf War and request from US DoD for standardization
- First version of ISBT 128 Standard published in 1994
- Extended to cover cell therapy and tissues in 2000
- Current work on organs, milk, tissue engineering/advanced therapies

Three strategies for global governance:
- Global consensus on a series of principles inherent to the human origin of MPHO – in particular prohibition on making the human body and its parts as such a source of financial gain
- Global use of ISBT 128 for all MPHO to ensure unique identification, optimal traceability and interoperability between countries, and across all MPHO, for both routine and emergency use
- Global collaboration on vigilance and surveillance of MPHO to support operation and oversight and to establish transparency for trust

- Globally unique identification numbers – ensures no duplication over a 100 year time period
- Standardized terminology – ensures a common understanding across multiple languages
- Standard for electronic transfer of information – allows rapid error free information transfer for critical information

- Traceability is essential for
  - Recall
  - Follow-up
  - Vigilance and Surveillance
- Traceability means being able to identify and track all products from a single donor
  - Whatever type (blood, cells, tissues, organs, milk etc.)
  - Wherever they are (local, national, global)
  - Over long time periods (e.g. 30 years from implant)
  - Across different regulatory frameworks

Raising Awareness of Member States Health Authorities to the role of ISBT 128 in Global Governance
- Improving communication between ICCBBA and Member States Health Authorities
- Facilitating access of low and middle income countries to ISBT 128
- Standardizing global V&S with the adoption of consistent ISBT 128 product terminology
Traceability

Effective traceability depends on:
- Unique identification of all products throughout the transfusion/transplantation pathway
- Accurate recording and transcription of data
- Reliable long term storage of information
- Linkage between information held in different organizations
- Rapid tracking

Published Consensus

Effective traceability requires:
- Electronic transfer of information
  - Bar codes
  - Scanners
- Common Terminology
  - Supports global activity data collection
  - Supports biovigilance and surveillance
  - Reduce risk of misunderstanding and error
- Information standards
  - Ensuring globally unique identification
  - Universally understood electronic coding of information

Supporting Organizations

Recent Activities

Technical Advisory Groups active in many fields (blood, cell therapy, tissue, ocular, milk, tissue engineering)
- Terminology Standardization
  - Widely endorsed global terminology developed and published for cell therapy and ocular tissue
  - WHO organ nomenclature developed
  - Consensus terminology developed for skin, and soft tissue; in development for cardio-vascular and bone

Terminology Harmonization

Standard terminology is important at several levels:
- Clinical application – requires detailed descriptions to distinguish clinically distinct variants
- Activity data collection – needs to capture data at a more generic level of description
- Vigilance and Surveillance – identifies trends by collating data across many product types
Terminology Harmonization
- ISBT 128 terminology describes MPHO at the clinical use level
- Incorporates classification at the level of Class of product
- Maps to higher level classification systems
  - Notify V&S Taxonomy
  - Eurocet data items
  - EU Generic descriptions

Tissues and Medical Devices
- Global initiative for standard identification of medical devices (UDI – unique device identification)
- In US, FDA final rule requires implementation of the UDI for all medical devices
- FDA regulates some tissue products as medical devices
- Risk that tissue identification may become more fragmented with different systems depending on the regulatory framework

ICCBBA has:
- Been approved by FDA as a UDI Issuing Agency.
- Developed an ISBT 128 UDI which is compatible with ISBT 128 for other tissues
- Signed a Memorandum of Understanding with the Global Medical Device Naming Agency (GMDN)
- Provided documentation to support tissue banks implementing an ISBT 128 UDI

Single European Code
Call for tender EAHC/2011/HEALTH/03
“Reference compendia for the application of a single European coding system for human tissues and cells”

Progress to date
- Tissue Establishment Compendium developed and populated
- Product Compendium developed and populated - supports ISBT 128
- Essential information for TE and CA documents published
- Translation tool developed and in test
- Draft Manual developed and being reviewed by CA’s
- Pilot evaluation due to start soon
**SEC and transparency**

- The TE Compendium is maintained by Member States Competent Authorities
- It contains all authorised/licensed tissue establishments in the EU
- The authorization status of each TE is available
- Lookup can be from the SEC or from the ISBT 128 Donation Identification Number

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**Current status of ISBT 128**

- Licensed Facilities
  - Blood: 4274 facilities in 56 countries
  - Cell Therapy: 453 facilities in 46 countries
  - Tissues: 96 facilities in 17 countries
  - Total: 4669 facilities in 77 countries
  - 118 Vendors licensed to support ISBT 128 in their products

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**ISBT 128 and Organ Transplant**

- An exciting new story for the next decade
- Basic organ nomenclature developed through WHO/ICCBBA SONG project
- ISBT 128 product codes available
- Provides the potential to link all MPHO from a single donor with one unique donation identification number

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**ICCBBA**

…an NGO in official relations with WHO working to deliver the vision of global standardization of terminology, coding and labeling for all medical products of human origin.
INTERNATIONAL COLLABORATION ACTIVITIES RELATED TO DONATION AND TRANSPLANTATION AT THE COUNCIL OF EUROPE

THE EXPERIENCE OF THE BLACK SEA AREA (BSA) PROJECT

Marta López Fraga, PhD
European Directorate for the Quality of Medicines & Healthcare (EDQM)

ORGAN DONATION: FACTS AND FIGURES

Each of these can save or heal a life

Transplantation is the unique moment in medicine where the life of a patient depends on the wish or will of another person.

HETEROGENEOUS TRANSPLANT SCENE IN EUROPE

Donation and Transplantation Worldwide

Actual donors from deceased persons, 2011

ORGAN DONATION: FACTS AND FIGURES

Kidneys are in the highest demand

In 2011, 2 patients were added to a kidney waiting list in Europe every hour.

That’s a total of 68,073 patients!

23,485 patients received a kidney
12 patients died every day due to lack of organs

Organ shortages remain the main obstacle in transplantation medicine!
IS TRANSPLANTATION A SHORT TERM TREATMENT?

WHAT IS THE COST OF TRANSPLANTATION?

Maximum Graft Survival (in Years)

Cost per QALY*

Treatment UK Pounds
Cholesterol control + diet 220
Pacemaker 1,100
Total hip arthroplasty 1,100
Kidney transplantation 4,710
Screening for breast cancer 5,780
Heart transplantation 7,840
Hypercholesterolemia: 25-39 y/o 14,150
Coronary Bypass 18,830
Peritoneal dialysis 19,870
Haemodialysis 21,970
Neurosurgical tumour removal 107,780

Potential savings by increasing renal transplants (2010) – France (ABM)

Scenario 1:
1% increase of grafts/year
Cumulative 180 more grafts 2011-2016
Cumulative savings: +37 million €

Scenario 2:
5% increase of grafts/year
Cumulative 980 more grafts 2011-2016
Cumulative savings: +198 million €

Average 10 yr savings per patient dialysis to transplant 600,000 €

Annual Cost of Treatment Methods for ESRD

Masson et al., 1993

*Quality adjusted life year


Source data: DG SANCO
**Savings from Renal Transplants Pay Back All Solid Organ Transplant Programs – Spain (ONT)**

Source data: DG SANCO

- **Annual savings per transplant**: 21.000 €
- **Renal transplants per year**: ~2006
- **Potential annual saving**: 46.144 €
- **Years needed to cover total tx cost**: 3.7
- **Cumulative Nr of tx patients**: ~19,000
- **Potential annual savings**: ~460 M €

**Organ transplantation is the most cost-effective treatment for end stage organ failure**

Transplantation therapy increases significantly the survival and quality of life of patients.

- Patients receiving renal transplants cost significantly less than patients on dialysis.
- Developing renal transplantation as part of the national health system brings savings that can cover for the costs of renal and other transplant programs.

**What can we do to improve the situation?**

The Council of Europe has been working in the area of organ, tissue and cell transplantation since 1987.
EUROPEAN COMMITTEE ON ORGAN TRANSPLANTATION (CD-P-TO)

77 representatives coming from 32 member states and 20 observer states and institutions (including the EC, WHO, CoE Committee on Bioethics and other Non-Governmental Organisations)

Principle:
Sharing of technical, scientific expertise in the health sciences. The member states provide experts to the EDQM so that common quality, safety and ethical standards can be elaborated jointly.

COUNCIL OF EUROPE TECHNICAL GUIDANCE

- Exhaustive guidelines to provide professionals with a useful overview of the most recent advancements in the field
- Ensure high level of quality and safety standards
- Contribute to the harmonisation of these activities among European countries and beyond, facilitating uniform standards and practices
- Comprehensive introduction on legislation and ethics
- Continuous update and maintenance

COUNCIL OF EUROPE LEGAL GUIDANCE

• Exhaustive guidelines to provide professionals with a useful overview of the most recent advancements in the field
• Ensure high level of quality and safety standards
• Contribute to the harmonisation of these activities among European countries and beyond, facilitating uniform standards and practices
• Comprehensive introduction on legislation and ethics
• Continuous update and maintenance

FIGHT AGAINST ORGAN TRAFFICKING

• Assist member states in improving their organ transplantation services whilst promoting the principle of voluntary non-renumerated donations
• Monitor practices in Europe and assess risks linked to procurement, storage and transplantation of organs, tissues and cells
• Provide guidelines on quality and safety standards and their implementation
• Examine the organizational structures involved in organ donation and transplantation in order to address the causes of organ shortage
• Ensure the transfer of knowledge and expertise throughout Europe
• Contribute to raise awareness among health professionals and general population about the importance and benefits of organs, tissues and cells donation

TRAFFICKING IN HUMAN BEINGS FOR THE PURPOSE OF ORGAN REMOVAL

The recruitment, transportation, transfer, harboring or receipt of persons,
by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person
for the purpose of exploitation...including the removal of organs

Consent irrelevant
Any of the following activities, when committed intentionally:

- The illicit removal of organs:
  - removal without the free, informed and specific consent of the living donor, or, in the case of the deceased donor, without the removal being authorized under its domestic law, OR
  - where in exchange for the removal of organs, the living donor, or a third party, has been offered or has received a financial gain or comparable advantage, OR
  - where in exchange for the removal of organs from a deceased donor, a third party has been offered or has received a financial gain or comparable advantage.

- The use of illicitly removed organs

- The preparation, preservation, storage, transportation, transfer, receipt, import and export of illicitly removed human organs

- The illicit solicitation or recruitment (of organ donors or recipients), offering and requesting of undue advantages (to health professionals or public officials)

- Aiding or abetting and attempt

The human body and its parts shall not, as such, give rise to financial gain or comparable advantage.

**Draft Council of Europe Convention Against Trafficking in Human Organs**


- Development of a new transplant law for Moldova
- Assistance in the elaboration of the acts and orders after the promulgation of the new law
- Establishment of the Transplant Agency
- Definition of the long term activities of the Transplant Agency
- Assistance in the definition of the financial and economic aspects of the activities coordinated by the Transplant Agency

**Addressing the Root Cause of Organ Shortage**

**International Collaboration Initiatives: Addressing Organ Shortage**

- Structure and enhance exchange of knowledge, expertise and good practices between member states
- Elaborate tailor-made programmes adapted to the economical socio-economical context of the different member states

**Black Sea Area (BSA) Project: Synergy Based on a Regional Network**

- Potential for more organs
- Potential to learn from each other

Kick Off meeting in Chisinau (Moldova) July 2011
**Specific Objectives of the BSA Project**

- to review the existing laws on transplantation of organs, tissues and cells and to promote the implementation of an effective legislative framework;
- to contribute to the establishment of national transplant authorities and programmes;
- to educate the public, professionals and media about transplantation;
- to identify areas where additional specialist expertise or training are required as the basis for a development strategy;
- to elaborate recommendations and action plans;
- to encourage networking and enhance international co-operation;
- to establish pilot actions to be developed in specific settings.

**BSA Project: Work Distribution**

- **Group A**
  - Russian Federation
  - Turkey
  - Romania
  - Established infrastructures and significant Tx activity
  - Focus on WP4: Clinical Practices

- **Group B**
  - Ukraine
  - Moldova
  - Bulgaria
  - Minimal activity
  - Focus on WP3: National Tx Authority

- **Group C**
  - Armenia
  - Azerbaijan
  - Georgia
  - No Tx activity although some Tx-related legislation exists
  - Focus on WP2: Legislation & Finances

**Structure of the BSA Project**

- **Participants**
  - National Focal Points
  - Government Contact Person (GCP)

- **Advisory Board**
  - Steering Committee
  - CD-in-IO

- **Partners & Supports**
  - Expert Organisations
  - Professional Societies

**Evaluation Methodology**

- Detailed country assessments using questionnaires
  - National questionnaire
  - Regional questionnaire
  - Hospital questionnaire for ICU doctors
  - Hospital questionnaire for donor coordinators

- Individual assessments of each country through site visits
  - Existing Tx legislation
  - Financial provisions in each country relative to health programmes and Tx activity
  - Existing infrastructure and Tx activity
  - Obstacles and institutional/structural problems related to development of Tx
  - Political will to develop Tx programmes
  - Public awareness campaigns

- Recommendations and setting of specific goals

- Evaluation after 1 year to see progress

**Black Sea Area (BSA) Project: Action Plan**

- WP 1: Coordination, dissemination, public awareness
  - Assessment of the existing transplant legislation
  - Elaboration of guidelines and effective laws according to local situation in each country
  - Assessment of political involvement and financial aspects of transplantation

- WP 2: Development of effective legislative and financial framework
  - Assessment of the existing transplant legislation
  - Elaboration of guidelines and effective laws according to local situation in each country
  - Assessment of political involvement and financial aspects of transplantation

- WP 3: Establishment of National Transplant Authorities
  - Implementation of rules, guidelines and standards for the organisation and functioning of the Agencies
  - Education and training of the medical and technical personnel of the Agencies

- WP 4: Clinical Practices
  - Analysis of the clinical practices of the donation and transplantation process
  - Specific training of doctors and nurses involved in transplantation activities

**Country Distribution**

- **Group A**
  - Russian Federation
  - Turkey
  - Romania
  - Established infrastructures and significantTx activity

- **Group B**
  - Ukraine
  - Moldova
  - Bulgaria
  - Minimal activity

- **Group C**
  - Armenia
  - Azerbaijan
  - Georgia
  - No Tx activity although some Tx-related legislation exists

**Romania Donors 2008 – Oct 2013 (p.m.p.)**

- Deceased D
- Living donors
- Linear (Deceased D)
- Linear (Living donors)
WHAT IS NEEDED FOR INTERNATIONAL COLLABORATION PROJECTS TO SUCCEED?

• Governmental support -> strong commitment and political involvement to invest in the development of a donation and transplantation programme

• Technical support -> working directly with national experts at a technical level

• International support -> transfer of know-how and expertise from countries with well-developed programmes

LESSONS LEARNED & TAKE HOME MESSAGES

• Transplantation programmes need to be transparent, fair and ethical

• There isn’t a universal recipe for success. Transplantation programmes need to be adapted to the individual socio-economic circumstances of each country

• Use resources wisely. You may not need to develop all programmes. Collaborate!

• The main factor impacting deceased donation rates is the ability of the system to identify possible organ donors and convert them into actual organ donors. This requires organisation, protocols, and training, among other things

• Don’t start building the house from the roof: an effective legislative and regulatory framework should be in place before focusing on clinical practices

• It is pointless to train professionals unless they are part of an officially recognised and supported national network

• Effective transplantation programmes require committed, continuous and sustainable political and financial investment and support
Organ donors in Spain:
Number & Annual Rate

There is great difference between the Spanish organ donation rates and those of many developed countries (donors pmp 2012).
50 PHYSICIANS FROM LATIN AMERICAN COUNTRIES WERE TRAINED IN DONATION AND MANAGEMENT

SIEMBRA (SOWING) PROJECT

CORDOBA DECLARATION OCTOBER 31st 2003

DECLARATION
• Creation of a training programme in transplant coordination
• Implement a Registry of donation and transplantation activity in Latin America
• Need of an Iberoamerican official forum of Donation and Transplantation

PUNTA CANA GROUP JUNE 2001

PUNTA CANA GROUP AND DECLARATION JUNE 2001

DECLARATION
• Approach to the society (media collaboration)
• Improve functioning organizational structures
• Enhance countries collaboration
• Governments Collaboration

LATINAMERICAN REGISTRY ON DONATION AND TRANSPLANTATION 2004: FIRST LATINAMERICAN DATA IN INTERNATIONAL DATABASES

MAIN OBJECTIVE
Promotion and development of programmes of donation and kidney transplantation in Latin America

COMPLEMENTARY OBJECTIVES
• Study Latin America situation: Legislation, economic and organizational issues related to transplantation
• Donation and transplantation activity
• Potential of deceased donation
• Design and pilot activities in concrete actions
• Training plans in donation and transplantation

Human Tissue and Organ Transplantation
World Health Assembly 2004
Resolution WHA57.18

TO PROVIDE, IN RESPONSE TO REQUESTS FROM MEMBER STATES, TECHNICAL SUPPORT FOR DEVELOPING SUITABLE TRANSPLANTATION OF CELLS, TISSUES OR ORGANS, IN PARTICULAR BY FACILITATING INTERNATIONAL COOPERATION
TO PROMOTE INTERNATIONAL COOPERATION SO AS TO INCREASE THE ACCESS OF CITIZENS TO THESE THERAPEUTIC PROCEDURES

SPAIN, IN CLOSE COOPERATION WITH THE PANAMERICAN HEALTH ORGANIZATION (PAHO) TAKES CARE OF THE DEVELOPMENT OF THIS RESOLUTION IN LATIN-AMERICAN COUNTRIES

MEETING ONT – PAHO
MONTEVIDEO – FEBRUARY 2005

MEETING CARTAGENA DE INDIAS
JUNE 2005

PROPOSAL:
TO CREATE A FORUM FOR COOPERATION
"BEROAMERICAN COUNCIL OF ORGAN DONATION AND TRANSPLANTATION"

PRIORITY ACTIONS
1. GLOBAL ANALYSIS OF DONATION AND TRANSPLANTATION IN LATINAMERICA
2. TRAINING PROGRAMS ON DONATION IN TRANSPLANTATION
3. STANDARD DEFINITIONS AND CLINICAL PRACTICE GUIDELINES
4. DEFINITION OF IMPROVEMENT AREAS AND COOPERATION IN MANAGEMENT AND ORGANIZATION
5. COMMUNICATION AND INFORMATION POLICIES
6. IMPROVEMENT STRATEGIES IN IMMUNOTHERAPY
7. ECONOMIC ANALYSIS OF DONATION AND TRANSPLANTATION
RENAL TRANSPLANTATION IS THE MOST ECONOMIC THERAPY FOR ESKD

DEPENDING OF THE COUNTRY, THE COST OF THE TRANSPLANT CAN BE RECOVERED IN A PERIOD OF 2 – 4 YEARS WHEN COMPARED WITH DIALYSIS

SALAMANCA DECLARATION

VII IBEROAMERICAN CONFERENCE OF HEALTH MINISTERS

APPROVAL OF THE IBEROAMERICAN COUNCIL AND NETWORK OF DONATION AND TRANSPLANTATION

FIRST MEETING MAR DEL PLATA NOVEMBER 15th 2005

GRANADA SEPTEMBER 15th 2005

IBEROAMERICAN COUNCIL/NETWORK OF ORGAN & TISSUE DONATION & TRANSPLANTATION

IBEROAMERICAN COUNCIL OF ORGAN & TISSUE DONATION AND TRANSPLANTATION

PERMANENT SECRETARY

OFFICIAL DELEGATES OF THE MEMBER COUNTRIES

• LATIN AMERICA
• SPAIN + PORTUGAL

OTHER SOCIETIES/BODIES

IBEROAMERICAN COUNCIL OF ORGAN & TISSUE DONATION AND TRANSPLANTATION

21 COUNTRIES + PAHO

SPAIN: PRESIDENCE & GENERAL SECRETARY

Ibero-American Summit of Heads of State and Governments Salamanca October 14th 2005

Declaration of Salamanca

18. Asimismo, promover acciones de sensibilización universal del derecho a la salud, de la puesta en práctica de las políticas para la promoción de la salud y la prevención de enfermedades, así como de la relevancia de las actividades de cooperación en el desarrollo y transplanto de políticas de bienestar en la promoción de la salud.
Cooperation among member states in ethical, organizational and legislation aspects in organ donation and transplantation.

More than 20 recommendations for donation and transplantation activity.

I.-MAR DEL PLATA
II.-MADRID
III.-MONTEVIDEO
IV.-PUNTA CANA
V.-SANTIAGO DE CHILE
VI.-LA HABANA
VII.-MEXICO D.F.
VIII.-BOGOTÁ
IX.-LIMA
X.-QUITO
XI.-BUENOS AIRES
XII.-QUITO
XIII.-PANAMA
X-CARTAGENA DE INDIAS

RCIDT MEETINGS

18 APPROVED RECOMMENDATIONS + 1 ACTION PLAN

PROFESSIONAL TRAINING

IBEROAMERICAN TRANSPLANT NEWSLETTER SINCE 2007

MAR DE PLATA DECLARATION
1. AUTOLOGOUS CORD BLOOD BANKS
2. PAPER AND TRAINING OF DONATION AND TRANSPLANTATION PROFESSIONALS
3. FUNCTIONS AND RESPONSIBILITIES OF A NATIONAL ORGANIZATION OF DONATION AND TRANSPLANTATION
4. QUALITY ASSURANCE PROGRAMME
5. ORGAN SHORTAGE SOLUTIONS
6. QUALITY AND SAFETY TISSUES AND CELLS
7. BIOETHICAL CONSIDERATIONS
8. BRAIN DEATH
9. TUMOURS CONSENSUS
10. CELL THERAPY
11. SEROLOGICAL DETERMINATIONS
12. DONOR MAINTENANCE...
¿WHAT ARE THE MAIN FACTORS WHICH ARE INFLUENCING ORGAN DONATION IN LATINAMERICA?

MAIN PROBLEMS IN LATIN AMERICA FOR ORGAN DONATION

- Resources and Infrastructure
- Health Care Systems Fragmentation
- No Coverage Most of Population
- Donation and TX Organization
- No Perception Relevant Topic
- Lack of Trained and Available Personnel
- No Donation Culture in Population

NEED OF A NATIONAL ORGANIZATION FOR DONATION AND TRANSPLANTATION

- Responsible of Organ Donation and Transplant Coordination (Organ Allocation, Waiting Lists,...)
- Official Support
- Real Action Capacity
- Professional and Society Implementation
- Adequate Technical Direction

MÁSTER ALIANZA

10 YEARS MASTER ALIANZA

OPENING O.N.T.

INTERNATIONAL MASTER DONATION AND TRANSPLANTATION

1. Organ Donors Spanish Model

BLOOD CORD BANKS

GENERAL COURSES

BARCELONA/ALICANTE/GRANADA

TWO MONTHS TUTORY WITH SPANISH COORDINATORS IN ALL SPANISH REGIONS

PRESENTATION OF FINAL PROJECT

MADRID/ BARCELONA

10 YEARS MASTER ALIANZA

MASTER ALIANZA:

325 PROFESSIONALS FROM ALL LATIN AMERICAN COUNTRIES

X EDITION 2014

Master Alianza 2005-2014
INFLUENCE ON COUNTRY REGULATION

COLOMBIA
TRANSPLANT TOURISM
NOW BANISHED THANKS TO THE ACTION OF
COLOMBIAN GOVERNMENT AND SUPPORTED
BY RCIDT

QUALITY CONTROL AND MANAGEMENT OF
TISSUE PROCUREMENT, EVALUATION,
PROCESSING, BANKING, DISTRIBUTION
AND APPLICATION OF HUMAN TISSUES
-EU DIRECTIVES 2004/23/EC & 2006/17/EC

HEALTH AUTHORITIES SUPPORT

ROUT SHEET FOR DONATION IMPROVEMENT

OBJECTIVE

DONATION IMPROVEMENT

CREATION/CONSOLIDATION
TRANSPLANT ORGANIZATION

TRAINING COURSES

TRAINED PROFESSIONAL

COUNTRY SPECIFIC FEATURES
FROM 2005 TO 2012: GROWING UP TO 50%
The role of Professional Societies in development of organ donation and transplantation

The Mission

The Transplantation Society will provide the focus for global leadership in transplantation:
• development of the science and clinical practice
• scientific communication
• continuing education
• guidance on the ethical practice

Membership of The Transplantation Society and its Sections will be a pre-requisite for effective professional clinical and scientific practice in the field of transplantation worldwide. The Transplantation Society will provide a comprehensive education program in the science and clinical practice of transplantation that improves patient outcomes, competence and performance of its members, the medical community and the general community.

Science
Clinical Care
Organ Donation
Special Interests
Public Policy
Advocacy

7 GOALS
1. Membership
2. Sections
3. Science
4. Education
5. Public Policy
6. Communications
7. Operations
8. Governance

8 STRATEGIES
1. 1. Membership services & Benefits
1.2 Affiliated national societies
1.3 Corporate membership
1.4 Council of Sections
2. 1. Sections
2.2 Council of Section Presidents
2.3 International Congress
2.4 Specific Section programs
2.5 Medical Science Development
2.6 Regional meetings
2.7 Specific major meetings
3. 1. Congress
3.2 Congress program
3.3 Congress education
3.4 Congress events
3.5 Congress meetings
3.6 Congress symposia
4. 1. CME Program
4.2 Congress educational programs
4.3 Congress scholarships
4.4 Congress awards
4.5 Congress communications
5. 1. Ethics Committee
5.2 WHO relationship
5.3 Declaration of Istanbul
5.4 GAT & society relationships
5.5 WHO NGO
5.6 WHO NGO
5.7 WHO NGO
5.8 WHO NGO
6. 1. www.tts.org
6.2 Journals
6.3 Newsletter
6.4 Member & non-member eblasts
6.5 IHQ Office
6.6 PCO Services
6.7 Marketing
6.8 Historical Archives
6.9 Governance

SECTIONS
MEMBERS
NATIONAL SOCIETIES
REGIONAL SOCIETIES
INTERNATIONAL SOCIETIES
COUNTRY AFFILIATES
ORGAN DONATION
GOVERNMENT ORGANISATIONS
MEMBERS
SECTIONS
TTS
DICG
WHO NGO
INTERNATIONAL ORGANISATIONS
GAT
To address the growing problems of organ sales, transplant tourism and trafficking in organ donors in the context of the global shortage of organs, a Summit Meeting was held in Istanbul of more than 150 representatives of scientific and medical bodies from 78 countries around the world, and including government officials, social scientists, and ethicists.

Monitoring and implementation of the principles of the DOI requires a formal structure
- Integrated into existing structures, leveraging off resources but an independent organization

Memorandum of Understanding TTS and ISN
- Co-Chairs
- Membership, terms, responsibilities
- Task Forces
An NGO in Official Relations with WHO/OMS

2010

21 May 2010  Resolution WHA 63.22
The Assembly Endorses WHO's Guiding Principles on Human Cell, Tissue and Organ Transplantation

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

2010

GP 1: Free donation and no purchase of human transplant as such, but cost & expenditures recovery
GP 2: Maximizing DD Protecting LD
GP 3: Promoting No advertising
GP 4: Protecting the vulnerable & incompetent
GP 5: Responsibly for transplant origin
GP 6: Justifiable fees
GP 7: Equitable allocation
GP 8: Monitoring long term outcomes: Quality and safety of procedures and products
GP 9: Transparency, openness to scrutiny, anonymity
GP 10: Legality of Organ Donation underpinned by Legislation
GP 11: Development of Regulations based on Legislation
GP 12: Oversight of Organ Donation and Transplantation by Health Dept. To ensure Transparency and Safety.
GP 13: Development of Agency to oversee Organ Donation
GP 14: Institution of Transplant and Organ Donor Registries
GP 15: Auditing of agencies
GP 16: Interaction with Transplant Units and Development of Policies to Ensure Use of Organs is Maximised and used by appropriately credentialed Centres

Self Sufficiency: Objective for Governments

The Madrid Resolution on Organ Donation & Transplantation: National Responsibility in Meeting the Needs of Patients, Guided by the WHO Principles

The Third Global Consultation on Organ Donation was organized by the World Health Organization in collaboration with the Spanish National Transplant Organization (CNT) and The Transplantation Society, and supported by the European Commission. The consultations held in Madrid from 23rd to 25th March 2010 brought together 167 government officials, representatives of international and medical bodies, and ethicists from 84 countries.

2010

2010

Development of an Ethical Organ Donor Policy

Public Education, Awareness & Involvement

Responsive

Capacities

Opportunities for Care

Responsibilities

NATIONAL ACCOUNTABILITIES
CAPACITY CONTROL
REGULATORY CONTROL
ETHICAL CONTEXT

- LEGISLATION
- DATA REGISTRIES
- HEALTHCARE FACILITIES
- HUMAN RESOURCES
- REGIONAL COOPERATION
- CULTURAL & RELIGIOUS ENVIRONMENT
- FUNDING

CAPACITY CONTROLS
REGULATORY CONTROLS
ETHICAL CONTEXT

- CKD
- RESPIRATORY
- CLD
- DIABETES
- CARDIAC
- OTHER

ACHIEVEMENTS

- EDUCATION
- VACCINATION
- SCREENING
- PREVENTION
- BRIDGING Rx
- DONATION
- TRANSPLANT
- RESEARCH
- OPPORTUNITIES FOR CARE

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