**Viral Hepatitis B and C are Prevalent in Asia**

**Hepatitis C prevalence, 2005**

Source: Hanafiah K et al. Hepatology 2013
Estimates are derived from a meta-analysis of data from 236 studies published between 1980 and 2007.

**Hepatitis B prevalence (adult), 2005**

Source: Ott J et al. Vaccine 2012
Estimates are derived from a meta-analysis of data from 396 studies published between 1980 and 2007.

---

**The need for Kidney Transplantation in Asia**

Over 2 million patients were being treated with dialysis in 2011. Nearly one quarter of this global dialysis population were being treated in Japan and China alone.

<table>
<thead>
<tr>
<th>Country</th>
<th>Population (millions)</th>
<th>% of world population</th>
<th>Dialysis patients (thousands)</th>
<th>% of world dialysis patients</th>
<th>Prevalence of dialysis (pmp)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>313</td>
<td>4%</td>
<td>420</td>
<td>19%</td>
<td>1,340</td>
</tr>
<tr>
<td>Japan</td>
<td>127</td>
<td>2%</td>
<td>302</td>
<td>14%</td>
<td>2,370</td>
</tr>
<tr>
<td>China</td>
<td>1,360</td>
<td>19%</td>
<td>200</td>
<td>9%</td>
<td>150</td>
</tr>
<tr>
<td>Brazil</td>
<td>205</td>
<td>3%</td>
<td>106</td>
<td>5%</td>
<td>520</td>
</tr>
<tr>
<td>Germany</td>
<td>81</td>
<td>1%</td>
<td>83</td>
<td>4%</td>
<td>1,020</td>
</tr>
<tr>
<td>Rep. Korea</td>
<td>50</td>
<td>&lt;1%</td>
<td>46</td>
<td>2%</td>
<td>920</td>
</tr>
<tr>
<td>Thailand</td>
<td>70</td>
<td>&lt;1%</td>
<td>43</td>
<td>2%</td>
<td>590</td>
</tr>
<tr>
<td>Malaysia</td>
<td>29</td>
<td>&lt;1%</td>
<td>24</td>
<td>1%</td>
<td>834</td>
</tr>
<tr>
<td>Global</td>
<td>6,963</td>
<td></td>
<td>2,164</td>
<td></td>
<td>210</td>
</tr>
</tbody>
</table>

Source: Official data in 2011 reported as part of the Global Burden of Disease 2011 study.

---

**Global distribution of transplantation activity**

2010

Transplantation rate (pmp):
- Pink: <12
- Red: 12-24
- Orange: 25-47
- Yellow: >47

Territory size is distorted in proportion to the number of organ transplants reported for each country in 2010.

Data source: Global Observatory on Donation and Transplantation; map courtesy of Dr. White.
Patients newly included on the waiting list for a kidney transplant in 2011, pmp

Kidney transplant rate in 2011, pmp

Source: Global Observatory on Donation and Transplantation (www.transplant-observatory.org)


Patients newly included on the waiting list for a kidney transplant in 2011, pmp

Kidney transplant rate in 2011, pmp

Source: Global Observatory on Donation and Transplantation (www.transplant-observatory.org)


The goal is not to find an ever-increasing supply of organs for transplantation, but rather to engage with transplantation in the context of a broader public health strategy for prevention of chronic organ failure.

Source: United States Renal Data System, Annual Report 2012

United States Centers for Disease Control and Prevention

Increased prevalence of diabetes and of treated ESKD with a primary diagnosis of diabetes

However, the incidence of Diabetes ESKD among the diabetic population has declined due to improved secondary prevention.

Source: United States Renal Data System, Annual Report 2012

The United States, Europe and Australia are starting to observe a decline in the rate of new patients starting renal replacement therapy.

In contrast, growth in dialysis populations has shifted to Asia, Latin America, the Middle East and Africa.

Prevention appears to be having an impact

Secondary... Primary

Meeting the needs of patients from a given population with an adequate provision of transplantation services and supply of organs from that population.

Diabetes and ESKD in the USA

Source: United States Renal Data System, Annual Report 2012

United States Centers for Disease Control and Prevention

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

The World Health Organization is currently expanding into a global, multidisciplinary framework for policy and practice.

Despite the global challenges, consistent and measurable improvements in donation, transplantation and outcomes have been achieved.
### The Self-Sufficiency Paradigm

**ORGAN Donation and Transplantation**

<table>
<thead>
<tr>
<th>PRINCIPLES</th>
<th>Solidarity</th>
<th>Reciprocity</th>
</tr>
</thead>
<tbody>
<tr>
<td>To meet patients’ needs:</td>
<td>1. Government responsibility</td>
<td>1. Legal framework</td>
</tr>
<tr>
<td>2. Equity</td>
<td>Organization</td>
<td>National Health Plan includes donation and transplantation</td>
</tr>
<tr>
<td>3. Education</td>
<td>In the burden of donation</td>
<td>Organ donation possible in as many circumstances of death as possible</td>
</tr>
<tr>
<td>4. Trust of the Public</td>
<td>In allocation (UHC)</td>
<td>=&gt; ORGANISATION</td>
</tr>
<tr>
<td>5. Professionalism</td>
<td>To donation</td>
<td>4. Comprehensive management of chronic kidney disease</td>
</tr>
<tr>
<td>6. Media associated to donation</td>
<td>To prevention</td>
<td>5. Health and death in school curriculum</td>
</tr>
</tbody>
</table>

Donation is a civic gesture, an expectation but not an exception.

### Medical Products of Human Origin (MPHO)

- Materials derived from the human body for clinical application.
- Despite the obvious differences in types of human biological materials used to create MPHO, and the range of therapeutic uses which they may serve, all MPHO have in common an origin and destination in the human body.

---

**WHO Organization-wide Initiative for Medical Products of Human Origin**

**GUIDING PRINCIPLE 10**

*WHO Guiding Principles On Human Cell, Tissue And Organ Transplantation*  
Endorsed by the sixty-third World Health Assembly in Resolution WHA 63.22

### Medical Products of Human Origin (MPHO)

<table>
<thead>
<tr>
<th>Recruitment</th>
<th>Selection</th>
<th>Clinical application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up</td>
<td>Procurement</td>
<td>Processing</td>
</tr>
<tr>
<td>Testing</td>
<td>Allocation</td>
<td>Issuing</td>
</tr>
<tr>
<td>Follow-up</td>
<td>Blood and blood products</td>
<td>Ethics – Safety &amp; Quality – Access</td>
</tr>
<tr>
<td>Cells</td>
<td>Tissues</td>
<td>Advanced Therapies</td>
</tr>
<tr>
<td>Organs</td>
<td>Gametes and Embryos</td>
<td>Plasma Derived Medicinal Products</td>
</tr>
<tr>
<td>Secretions and excretions…</td>
<td>….. Personalized medicine</td>
<td></td>
</tr>
</tbody>
</table>
Recognizing Humanity in Medical Products of Human Origin

The Human Body and its Parts as Such
Not the Source of Financial Gain

3. Global Governance Tools for MPHO
1. Principles inherent to the Human Origin
   • 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 ISBT 128 within 10 years
3. Global vigilance and surveillance
   • NOTIFY project for Vigilance and Surveillance of MPHO
   • Using at best the global experience of adverse incidents

The WHO Wide Initiative for MPHO
April 2013 - Programmed Budget 2014-2015

-1- Items for Standards of Practice for MPHO

• Responsibility for the provision of MPHO placed with authorities and through them the individual citizen and resident;

• Equity as a goal, in the burden of donation and in allocation of MPHO;

• Prohibition of financial gain on the human body and its parts as such and where profit is not forbidden, guarantee of transparency;

• Genuine consent of donors and recipients and protection of the incompetent;

• Use of MPHO justified by evidence and absence of comparable alternative;

• Duty to constantly optimize the safety, quality and efficacy of procurement, process and clinical application of MPHO;

• Traceability and accountability mandated throughout the process, from donors to recipients, including long term outcomes and vigilance and surveillance under the oversight of competent authorities;

• Transparency and openness to scrutiny indispensable while confidentiality and anonyminy when required must be preserved.
Transparency

Activities and practices

"Transparency — especially when things go wrong — is increasingly considered necessary to improving the quality of health care. By being candid with both patients and clinicians, health care organizations can promote their leaders’ accountability for safer systems, better engage clinicians in improvement efforts, and engender greater patient trust.” — Allen Kachalia

Role of Scientific and Professional Societies

The WHO-Wide Initiative for MPHOs

Towards an overarching level of requirement specific to MPHOs

EB 134
- Review of the implementation of resolutions WHA63.12 and WHA63.22 on transfusion and transplantation
- WHA67
  - Side event on MPHOs
  - Review of the implementation of resolutions WHA63.12 and WHA63.22
  - Request to WHO for a report on overarching issues associated to the human origin of therapeutics

Regional and Global consultation process

WHA68/69 Resolution on MPHOs
- Global Standards for MPHOs

Thank you

nunezj@who.int
noell@who.int
Update on WHO activities and priorities in cell, tissue and organ transplantation

Global Observatory on Donation and Transplantation
Organs Transplanted Globally in 2012

≈ 114,690 organs transplanted
≈ 10% of estimated global needs

<table>
<thead>
<tr>
<th>Kidney</th>
<th>Liver</th>
<th>Heart</th>
<th>Lung</th>
<th>Pancreas</th>
</tr>
</thead>
<tbody>
<tr>
<td>77818</td>
<td>23986</td>
<td>5935</td>
<td>4359</td>
<td>2423</td>
</tr>
</tbody>
</table>

≈ 1.81% increase over 2011

109 countries reported to the Global Observatory on Organ Donation and Transplantation
South Africa, India and China are 2010 estimates

≈ but only 2-3% of world's deceased donors

There are more people living inside this circle than outside of it.
Tissues

- 1.9 million tissue grafts distributed by AATB accredited tissue banks each year
- > 100,000 tissues imported into Korea in one year
- > 200,000 tissues grafts a year in Germany
- 5,000 cornea transplants in Italy each year
- 46,000 corneas distributed by Sri Lanka Eye Bank over 30 years

Update on WHO activities and priorities in cell, tissue and organ transplantation

Distribution of stem cell donors

- North America: 37%
- Europe: 14%
- Asia: 11%
- South America: 1%
- Others: 11%

HSCT

- > 50,000 patients/year
- 22 millions donors
Transplantation Progresses on an unsteady scale

Solidarity
Equity
Respects for Dignity

Loss of Dignity
Market inequtiy
Exploitation

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

GP 1: Free donation and no purchase of human transplant as such, but cost & expense recovery.

GP 2: Maximizing DD
Protecting LD

GP 3: Promoting
No advertising

GP 4: Protecting the incompetent

GP 5: Justifiable fees

GP 6: Equitable allocation

GP 7: For transplant origin

GP 8: Reasonability

GP 9: Monitoring long term outcomes. Quality and safety of procedures and products

GP 10: Transparency, openness to scrutiny, anonymity
Guidance on criteria for the determination of death

WHO team
- 8-10 experts (neurologist, intensivist, cardiologist etc)

Increase global visibility of the “GODT”

Vigilance and surveillance

Increase global visibility of the “GODT”

Value transplantation and increase the motivation to donate among people

Better know the countries’/regions’ situation to develop the appropriate policies to increase donation rates.

Formulated the idea of language specific web interfaces that would help non-English speakers to benefit from the NOTIFY project and conversely would help the NOTIFY project by allowing the input of cases initially not published in English.
**Most spoken languages**

- English: 478
- French: 206
- Japanese: 226
- Portuguese: 284
- Arabic: 392
- Russian: 1215
- Spanish: 125
- Chinese: 127

Millions inhabitants

- Search for relevant cases in their own language
- Translated into English
- Send it to the NL editorial group
- Upload

**WHO activities and priorities**

- Guidance on criteria for the determination of death
- Increase global visibility of the “GODT”
- Vigilance and surveillance
- Emerging areas: Xenotransplantation, Regenerative Medicine
WHO activities and priorities

• To review the current status of xenotransplantation science and practice
• To strengthen wider collaboration among members and with other societies for enhancement of research activities
• To encourage transparency in xenotransplantation related activities

Guidance on criteria for the determination of death
Increase global visibility of the “GODT”
Vigilance and surveillance
Emerging areas: Xenotransplantation Regenerative Medicine
Strengthening Global Network

Promote close collaboration with Health Authorities, Scientific and Professional Societies in charge of national policies.
Establish a structured regional working group in WPRO for transplantation in light of the European and Latin-American experience
Thank you

noelli@who.int
nunezj@who.int
http://www.who.int/transplantation/en/
Essential legal and organizational requirements for national cell, tissue and organ transplantation services

Jeremy Chapman
Sydney

Deceased Donor Transplantation

Legislative and Regulatory Framework

Living Donor Transplantation

Surgical Team

HLA Lab

Funding Mechanisms

Data Systems

Post Tx Care

Drug program

Acute Dialysis Capacity

KIDNEY

Deceased Donor

Diagnosis of death

Donor medical risk assessment

Recipient(s) Crossmatch

Surgical retrieval

One National Waiting list

Transplant facility

Transplant follow up

Key:

Medical Protocol

Ministry regulation

Living Donor

Donor Assessment

Surgical retrieval

Deceased Donor

Living Donor

Legislative and Regulatory Framework

Deceased Donor Transplantation

Chronic Dialysis Program

Organ/Tissue Procurement /Banking program

ICU/Brain Death

Waiting List and Allocation

POST TX CARE

Funding Mechanisms

Drug program

Data Systems

Post Tx Care

On Call Team

Surgical retrieval

Recipient(s) Crossmatch

Transplant facility

Transplant follow up

Key:

Medical Protocol

Ministry regulation

Deceased Donor Transplantation

Death of a Living Liver Donor: Opening Pandora’s Box
Critical issues in determining the basis of legislation on human organ, tissue and cell transplantation:

- **Compatibility with WHO Guiding Principles and Declaration of Istanbul**
- **The extent of inclusions**
- **Basis of Consent**
- **The definitions of Death**

**WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation**

- **GP 1** Consent
- **GP 2** Death by the competent
- **GP 3** Maximising CDO Protecting LD
- **GP 4** Protecting the incompetent
- **GP 5** Free donation and no purchase of human transplant as such, but cost & expenditures recovery
- **GP 6** Promoting No advertising
- **GP 7** Responsibility for transplant origin
- **GP 8** Justifiable laws
- **GP 9** Equitable allocation
- **GP 10** Monitoring long term outcomes. Quality and safety of procedures and products
- **GP 11** Transparency, openness to scrutiny, anonymity

**The context in Law for Organ, Tissue and Cell Transplantation**

- Ownership and Gift laws
- Definition of nationality
- Human Organ & Tissue Legislation and regulations
- Consent framework
- Therapeutic goods laws regulations
- Public Health care laws regulations
- Private Health care laws regulations
- Customs and excise laws regulations

**The Madrid Resolution**

- **CAPACITIES**
  - Legislation
  - Data registries
  - Healthcare facilities
  - Human resources
  - Regional coordination
  - Cultural & religious environment

- **ACHIEVEMENTS**
  - Sufficient
  - ACHIEVEMENTS
  - Responsiveness

- **OCCUPATIONAL FEES FOR CARE**
  - Education
  - Immunization
  - Screening
  - Prevention
  - Bridging & transition
  - Donation & transplant research

- **SUFFICIENCY**
  - Why are they intertwined?
  - Indistinct and changing limits in human application
  - Practices with one impact the others
  - No national borders for safety or ethical risks
  - Yet there are strong differences and particularities between sub-classes of MPOHO
  - But the self-sufficiency paradigm applies to all, as MPH0 from humans for humans, involve SOCIETY
  - MPOHO demand a consistency of practices. A set of common global governance principles is necessary
Legal Principles: Gift Law

- Gift law principles may have important legal consequences for donation
  - Legally binding transfer
  - Prohibition on valuable consideration
  - Altruism and volunteerism

Presumed Consent defined for donation

The legal authority to recover organs from deceased adult individuals unless a refusal to donate was registered.

Primary Legal Models

- Explicit Consent = OPT IN
- Presumed Consent = OPT OUT

Countries with Explicit Consent = Opt in

- Argentina
- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Greece
- Hungary
- Ireland
- Israel
- Japan
- Jordan
- Korea
- Lebanon
- Malaysia
- Lithuania
- Mexico
- Netherlands
- New Zealand
- Norway
- Panama
- Paraguay
- Peru
- Poland
- Portugal
- Singapore
- Slovak Republic
- Slovenia
- Spain
- Sweden
- United Kingdom
- United States of America
- Venezuela

Countries with Presumed Consent = Opt Out

- Australia
- Canada
- Chile
- Cuba
- Croatia
- Cyprus
- Czech Republic
- Estonia
- Finland
- France
- Greece
- Hungary
- Ireland
- Japan
- Jordan

First Person Consent

Adult individuals have the right to make a legally binding anatomical gift prior to death.
The function of the brain is irreplaceable.

DEATH

Brain scan

ELIGIBLE DCD DONOR
A medically suitable person who has been declared dead based on the irreversible absence of circulatory and respiratory functions as stipulated by the law of the relevant jurisdiction, within a time frame that enables organ recovery.

POTENTIAL DBD DONOR
A person whose clinical condition is suspected to fulfill brain death criteria.

ELIGIBLE DBD DONOR
A medically suitable person who has been declared dead based on neurologic criteria as stipulated by the law of the relevant jurisdiction.

Critical pathways for organ donation *
POSSIBLE DECEASED ORGAN DONOR
A patient with a devastating brain injury or lesion OR a patient with circulatory failure AND apparently medically suitable for organ donation

UTILIZED DCD DONOR
An actual donor from whom at least one organ was transplanted.

Reasons why a potential donor does not become a utilized donor

System
• Failure to identify/refer a potential or eligible donor
• Brain death diagnosis not confirmed (e.g. does not fulfill criteria) or completed (e.g. lack of technical resources or clinician to make diagnosis or perform confirmatory tests)
• Circulatory death not declared within the appropriate time frame.
• Logistical problems (e.g. no recovery team)
• Lack of appropriate recipient (e.g. child, blood type, serology positive)

Donor/Organ
• Medical unsuitability (e.g. serology positive, neoplasia)
• Haemodynamic instability / unanticipated cardiac arrest
• Anatomical, histological and/or functional abnormalities of organs
• Organs damaged during recovery
• Inadequate perfusion of organs or thrombosis

Permission
• Expressed intent of deceased not to be donor
• Relative's refusal of permission for organ donation
• Refusal by coroner or other judicial officer to allow donation for forensic reasons

POTENTIAL DCD DONOR
A. A person whose circulatory and respiratory functions have ceased and resuscitative measures are not to be attempted or continued.
B. A person in whom the cessation of circulatory and respiratory functions is anticipated to occur within a time frame that will enable organ recovery.

Donation after Brain Death (DBD)
Treating physician to identify/refer a potential donor

ACTUAL DBD DONOR
A consented eligible donor:
A. In whom an operative incision was made with the intent of organ recovery for the purpose of transplantation.
B. From whom at least one organ was recovered for the purpose of transplantation.

UTILIZED DBD DONOR
An actual donor from whom at least one organ was transplanted.

Donation after Circulatory Death (DCD)

ACTUAL DCD DONOR
A consented eligible donor:
A. In whom an operative incision was made with the intent of organ recovery for the purpose of transplantation.
B. From whom at least one organ was recovered for the purpose of transplantation.

The "dead donor rule" must be respected. That is, patients may only become donors after death, and the recovery of organs must not cause a donor's death.

Transplant Type
- Kidney – living donor
- Kidney/Organs – deceased donor
- Cornea tissue
- imported Cornea tissue – local
- Cell transplant
- Xeno transplant
- Gametes
- Blood and blood products

Hospital infrastructure
National infrastructure
Regulatory framework
Legislative framework

Scope of consideration for implementation

* The Ad Hoc Committee includes Henry K. Beecher, MD, chairman; Raymond D. Adams, MD; Clifford Rogers, MD; Williams J. Cronin, ELM; Shobhy; Denis P. Brown, MD; Denis L. Fennessy, MD; John Florio, MD, James G. Mezrich, MD, John M. Murny, MD, Delph Potes, TBO; Robert Stack, MD, and William Street, MD.

A Definition of Irreversible Cornea
Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death

JAMA. Aug 5, 1968 • Vol 205, No 6
GOVERNMENT OF FIJI

THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES DECREE 2013

IN exercise of the powers vested in me as the President of the Republic of Fiji and Commander in Chief of the Republic of Fiji Military Forces by virtue of the Executive Authority of Fiji Decree … 2009, I hereby make the following Decree -

TO REGULATE THE REMOVAL, STORAGE, AND TRANSPLANTATION OF HUMAN ORGANS FOR THERAPEUTIC PURPOSES AND FOR THE PREVENTION OF COMMERCIAL DEALINGS IN HUMAN ORGANS FOR MATTERS CONNECTED WITH OR INCIDENTAL THERETO.

WHEREAS IT IS EXPEDIENT TO PROVIDE FOR THE REGULATION OF REMOVAL, STORAGE, AND TRANSPLANTATION OF HUMAN ORGANS FOR THERAPEUTIC PURPOSES AND FOR THE PREVENTION OF COMMERCIAL DEALINGS IN HUMAN ORGANS.

PART 1- PRELIMINARY

1. Short title and commencement

This Decree may be called the Transplantation of Human Organs Decree, 2013 and shall come into force on a date appointed by the Minister by notice published in the Gazette.

2. Interpretation and Definitions

(1). In this Decree, unless the context otherwise requires:

"Advertisement" includes any form of advertising whether to the public generally or to any section of the public or individually to selected persons;

"Appropriate Authority" means the Appropriate Authority appointed under section 30.

"Authorization Committee" means the Committee constituted under section 60.

"blood product" means a product or extract derived or extracted from blood by any process of manufacture.

"child" means a person who has not attained the age of 18 years.

"designated officer" means:

(a) in relation to a hospital, a person appointed for the time being under section 4 (1) to be a designated officer for a hospital, or

Parts:

1 Preliminary and Definitions
2 Donations of tissue by living persons
3 Use of tissue removed during medical, dental or surgical treatment
4 Removal of Tissue after death
5 Regulation of Hospitals
6 Appropriate Authority
7 Registration of Hospitals
8 Prohibition of trading in tissue
9 Definition of Death
10 Enforcement
11 Miscellaneous

A Legal Framework

Questions:
1 What about minors & the legally incompetent
2 What about non-national recipients
3 What about non-national & unrelated donors
4 Ban or regulate advanced cell therapies
5 Private versus Public Hospitals
6 Minister advised by a committee for problems
7 Ethics committee review – is this self governing
8 How to define when reasonable fees become profiteering and commercialism
9 Is the medical system capable
10 What penalty system will work
11 How is allocation of a scarce resource managed

Crosswalk with WHO Guiding Principles
Global Observatory on Donation and Transplantation (GODT)

International Technical Consultation on Cell, Tissue and Organ Donation and Transplantation in The Western Pacific Region.
20 to 21 February 2014, Seoul, Republic of Korea.
Ms Mux Carmona (mcarmona@msssi.es)
Organización Nacional de Trasplantes (ONT), Spain

Background

In response to the request made in Resolution WHA57.18 in 2004. This request was reiterated in Resolution WHA63.22 in 2010.

2005 URGES Member States:
[7] to collaborate in collecting data including adverse events and reactions on the practices, safety, quality, efficacy, epidemiology and ethics of donation and transplantation;
REQUESTS the Director-General:
[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;

http://www.transplant-observatory.org

-Resources covered by ONT
-ONT officially designated WHO CC

• 194 Member States in the six WHO Regions: AFR, AMR, EMR, EUR, SEAR, WPR

Questionnaire

Ad hoc questionnaire to the national focal points
Reminders (E-mail)
Reception of data
Deadlines: every year in Q2/Q3
Revision of data and clarification whenever discrepancies are found (by E-mail or phone)
Data entry in the database
Validation, data check and final approval by Member States

Calculation of indicators of donation and transplantation (country, regional and global estimates)
Further analysis
Graphics and official maps
Publication in the GODT website
Presentations / Other
Journals

Global Database: Settings

Scope
• 194 Member States in the six WHO Regions: AFR, AMR, EMR, EUR, SEAR, WPR

Content
• Information for organs: legislative and organizational aspects and annual donation and transplantation activities
• Available to everyone
• Information for tissues and cells: A similar process will be followed

Source of data
• National Health Authorities or officially designated by them

Methodology: collection of annual activity data

Ad hoc questionnaire to the national focal points
Reminders (E-mail)
Reception of data
Deadlines: every year in Q2/Q3
Revision of data and clarification whenever discrepancies are found (by E-mail or phone)
Data entry in the database
Validation, data check and final approval by Member States

Calculation of indicators of donation and transplantation (country, regional and global estimates)
Further analysis
Graphics and official maps
Publication in the GODT website
Presentations / Other
Journals
**Conclusions**

- The knowledge of demand for transplantation, availability of organs from deceased and living donors and the access to transplantation is essential to monitor global trends in transplantation needs.

- Information regarding the existence of legislation and regulatory oversight is fundamental to ensure safety and the ethical practice of organ donation and transplantation in accordance with international standards.

- The global availability of information is prerequisite to demonstrate transparency, equity and to monitor transplant systems in countries.

**Areas of improvement:**
- Reinforce the collaboration between NHA and professionals, and WHO/ONT for the collection of data (special attention should be paid for tissues and cells)

The global database is the result of dedicated efforts to strengthen the network of focal points, and it is the result of their valuable contribution to providing annual data.

**Thank you...**

Mar Carmona: mcarmona@msssi.es
What we have done for promoting organ donation in Korea?
- recognizing the problem and finding the solution -

Won-Hyun Cho, MD.
Keimyung University School of Medicine,
Vitallink - Korean Network for Organ Donation

WHO technical consultation 2014, Seoul

Number of Deceased donor before legislation of transplantation law

<table>
<thead>
<tr>
<th>Year</th>
<th>Donor</th>
<th>Total</th>
<th>Kidney</th>
<th>Liver</th>
<th>Pancreas</th>
<th>Pressure to donor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1969</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>1979</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>1988</td>
<td>25</td>
<td>10</td>
<td>10</td>
<td>5</td>
<td>0</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>1993</td>
<td>150</td>
<td>49</td>
<td>49</td>
<td>49</td>
<td>10</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>1995</td>
<td>220</td>
<td>110</td>
<td>110</td>
<td>110</td>
<td>10</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>1999</td>
<td>320</td>
<td>200</td>
<td>200</td>
<td>200</td>
<td>200</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>2000</td>
<td>360</td>
<td>230</td>
<td>230</td>
<td>230</td>
<td>230</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>2001</td>
<td>400</td>
<td>250</td>
<td>250</td>
<td>250</td>
<td>250</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>2002</td>
<td>450</td>
<td>300</td>
<td>300</td>
<td>300</td>
<td>300</td>
<td>&lt; 3</td>
</tr>
</tbody>
</table>

1969: LDKK
1979: DDKK
1988: DDLT
1993: KMA
1995: Brain Death
1999: Transplantation law
2000: KONOS

Legislation of organ transplantation law in 1999
- Necessity of Brain death law
- Need nationwide organ allocation system
- Need organ pressure organization
- Need nationwide waiting list
- Prohibit organ trade inside of Korea
- Transplantation law from 2000

Recognition of problem and solution in 1999

Organ donation Promotion by each transplant center
1969: LDKK
1979: DDKK
1988: DDLT
1993: KMA
1995: Brain Death
1999: Transplantation law
2000: KONOS

Traveling through Desert

Number of Deceased donor in Korea

<table>
<thead>
<tr>
<th>Year</th>
<th>Procure rate / donor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1969</td>
<td>3.4 pmp</td>
</tr>
<tr>
<td>1979</td>
<td>1.09 pmp</td>
</tr>
<tr>
<td>1988</td>
<td>1.08 pmp</td>
</tr>
<tr>
<td>1993</td>
<td>0.75 pmp</td>
</tr>
<tr>
<td>1995</td>
<td>1.41 pmp</td>
</tr>
<tr>
<td>1999</td>
<td>1.77 pmp</td>
</tr>
<tr>
<td>2000</td>
<td>1.87 pmp</td>
</tr>
<tr>
<td>2001</td>
<td>2.88 pmp</td>
</tr>
<tr>
<td>2002</td>
<td>3.00 pmp</td>
</tr>
</tbody>
</table>

Legislation of organ transplantation law
- Necessity of Brain death law
- Need nationwide organ allocation system
- Need organ pressure organization
- Need nationwide waiting list
- Prohibit organ trade inside of Korea
- Transplantation law from 2000
After legislation but organ donation is still not sufficient

Transplant tourism
Prolonged waiting time than before
Kidnap ? Murder?

Istanbul declaration
Ask self sufficiency

Recognizing and solution of organ donation system (2007 – 2009)

- System
  - Need revision of Transplant law for required reporting system
  - Need independent OPO system for organ procure

- Medical : How to increase procure rate per donor
  - Transplant center meeting – cooperation during procurement
  - Revise allocation system (region, status)

- Social : to get more consensus for organ donation
  - Expanded campaign for donation to students
  - Communication with Police office, MoH, Congress, Journalist
  - Donor family management, bereavement, public awareness
  - Realize problems of living donor safety

How can we solve these problems?

Increase organ donation, especially Deceased donor

Types of organ donor, donation rate and transplantation rate per million population

<table>
<thead>
<tr>
<th>Country</th>
<th>Spain</th>
<th>USA</th>
<th>France</th>
<th>Italy</th>
<th>UK</th>
<th>Korea 2005</th>
<th>Korea 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total population (million)</td>
<td>44.1</td>
<td>298.2</td>
<td>61.8</td>
<td>55.8</td>
<td>59.0</td>
<td>62.5</td>
<td>46.7</td>
</tr>
<tr>
<td>No. of Deceased</td>
<td>1,546</td>
<td>7,593</td>
<td>1,371</td>
<td>1,197</td>
<td>753</td>
<td>1,220</td>
<td>91</td>
</tr>
<tr>
<td>Donation rate / prep</td>
<td>35.1</td>
<td>25.5</td>
<td>22.2</td>
<td>21</td>
<td>12.8</td>
<td>14.8</td>
<td>1.87</td>
</tr>
<tr>
<td>No. of TPX from DD</td>
<td>3,720</td>
<td>21,225</td>
<td>4,152</td>
<td>3,281</td>
<td>2,332</td>
<td>3,814</td>
<td>385</td>
</tr>
<tr>
<td>TPX rate / prep</td>
<td>84.3</td>
<td>71.2</td>
<td>67.1</td>
<td>57.3</td>
<td>39.5</td>
<td>47.4</td>
<td>5.85</td>
</tr>
<tr>
<td>No. of TPX from LD</td>
<td>112</td>
<td>6,586</td>
<td>345</td>
<td>129</td>
<td>551</td>
<td>650</td>
<td>1,270</td>
</tr>
<tr>
<td>TPX rate / prep</td>
<td>2.5</td>
<td>23.1</td>
<td>4.0</td>
<td>2.3</td>
<td>9.3</td>
<td>7.2</td>
<td>26.1</td>
</tr>
</tbody>
</table>

Solution

Increase the number of deceased donor!
Activation of deceased donor transplantation

National factors increasing organ donation rate

- Potential for donation ---- MRR first
- To donor hospital or doctor --- revise law
  - Required referral
  - Required request
- Legislative environment --- need national consensus
  - Opting-out (presumed consent)
  - Opting-in (explicit consent)

The Eurotransplant experience
Medical director should inform the fact when they treated suspected brain death patient to OPO and the director of OPO must report that to KONOS.

Revised Transplant Law in 2010

Publish educational materials

Educate to students

Donor Sound of recipient

Education to point of contact

vitallink.or.kr

Networking between NGOs

Korean Organ Donation Network
(KoDoNet)

Organ donation campaign by NGOs in Korea

From early 1990s Networking from 2010

KODA(Korea Organ Donation Agency)

KODA (Korea Organ Donation Agency)
Networking of various NGOs for effective, professional campaign from 2010

Start Nationwide Transplant Database from 2009

How about result?
Recent action direction of Vitallink

- To achieve 10 million donor card
- Cooperative work with Hospital director, Self-governing officer, Journalist
- Visual activity of the transplanted recipient to the public: WTG
- Mobile campaign using smartphone

Campaign to have Donor Card from 1,000,000 to 10,000,000

<table>
<thead>
<tr>
<th>Year</th>
<th>Donor card holder</th>
<th>Actual donor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2009 2012 2013</td>
<td>2014 2015</td>
</tr>
<tr>
<td>Before 2000</td>
<td>47,224</td>
<td>1 1 1 1 1</td>
</tr>
<tr>
<td>2000-2003</td>
<td>15,949</td>
<td>1 1 1 1 1</td>
</tr>
<tr>
<td>2004</td>
<td>15,521</td>
<td>1 1 1 1 1</td>
</tr>
<tr>
<td>2005</td>
<td>77,166</td>
<td>1 2 100 1</td>
</tr>
<tr>
<td>2006</td>
<td>90,732</td>
<td>6 6 300 3</td>
</tr>
<tr>
<td>2007</td>
<td>81,169</td>
<td>7 7 200 7</td>
</tr>
<tr>
<td>2008</td>
<td>74,481</td>
<td>4 4 200 4</td>
</tr>
<tr>
<td>2009</td>
<td>185,046</td>
<td>8 8 200 8</td>
</tr>
<tr>
<td>2010</td>
<td>124,377</td>
<td>11 100 1</td>
</tr>
<tr>
<td>2011</td>
<td>94,737</td>
<td>14 100 1</td>
</tr>
<tr>
<td>2012</td>
<td>87,754</td>
<td>11 100 1</td>
</tr>
<tr>
<td>2013</td>
<td>118,871</td>
<td>11 100 1</td>
</tr>
<tr>
<td>2020</td>
<td>(1,000,000)</td>
<td>11 100 1</td>
</tr>
</tbody>
</table>

World Transplant Games

Increase organ donation rate about 15%

Mount Climb by Recipients

2008 Seoul NU team

Donor family & people realized that their decision of donation is not a useless one but a precious sacrifice, and proud of it!
Pattern of Campaign

**Why SNS?**

- Easily spread information to the public
- Can communicate

**Have you ever heard about organ shortage and its related problems?**

- No?
- No!
- Never heard
- No…

- Repeat education and campaign!

**Discussion about living donor safety & support to the donor**

- National Assembly

- Raise ethical problem in transplantation and organ donation to the public

**Infrastructures for Successful Organ Transplantation**

- Healthcare Infrastructure
- Organ Procurement Organization (OPO)
- Public Education (NGOs)
- Organ Allocation
- Regulation and Coordination
- Database

**Vitallink International**

- Transplantation in Korea and
- Sharing vision between Asian countries

- Share our experience and joint growth in Asian countries
Self-sufficiency of organ donor: not achieved at one moment, not by single action of campaign

It begins with a small ball of snow!

If we roll that snow ball again and again, we can make snowman